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No. 80-2182
No. 81-11

In The
Supreme Court of the United States
October Term, 1981

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INWOOD LABORATORIES, INC., et al.,
Petitioners,

vs.

IVES LABORATORIES, INC.,
Respondent.

◆

DARBY DRUG CO., INC., et al.,
Petitioners,

vs.

IVES LABORATORIES, INC.,
Respondent.

◆

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

JOINT APPENDIX
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MILTON A. BASS
BASS, ULLMAN & LUSTIGMAN
Counsel for Petitioner
Inwood Laboratories, Inc.
747 Third Avenue
New York, New York 10017
(212) 751-9494

ROBERT V. MARROW
SALON, MARROW, DYCKMAN & KELLMAN
Counsel for Petitioners
Darby Drug Co., Inc.
MD Pharmaceutical Co., Inc.
Rugby Laboratories, Inc., and
Sherry Pharmaceutical Co., Inc.
41 East 42nd Street
New York, New York 10017
(212) 661-7100

MARIE V. DRISCOLL
COOPER, DUNHAM, CLARK, GRIFFIN & MORAN
Counsel for Respondent
Ives Laboratories, Inc.
30 Rockefeller Plaza
New York, New York 10112
(212) 977-9550

PETER T. COBRIN
KIRSCHSTEIN, KIRSCHSTEIN, OTTINGER AND COBRIN, P.C.
Counsel for Petitioner
Premo Laboratories, Inc.
666 Fifth Avenue
New York, New York 10103
(212) 581-8770

Petition for *Certiorari* Filed June 24, 1981
***Certiorari* Granted October 13, 1981**

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OPINIONS BELOW

The five opinions rendered below were reprinted in the Appendices to the Petition of Inwood Laboratories, Inc. ("Inwood") and Premo Pharmaceutical Laboratories, Inc. ("Premo") for *Certiorari*, No. 80-2182, in chronological order. Pursuant to Supreme Court Rule 33.1, they have not been reproduced again in the joint appendix, and appear in the Appendices to the Petition ("Pet.App.") as indexed below:

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Appendix A — Opinion of the United States District Court for the Eastern District of New York, *Ives Laboratories, Inc.* v. *Darby Drug Co., Inc.*, 455 F.Supp. 939 (E.D.N.Y. 1978) 1a-27a

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RELEVANT DOCKET ENTRIES IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK PURSUANT TO SUPREME COURT RULE 30.5

Date	Entry
2/28/78	Complaint filed. Summons issued.
	***
3/20/78	Notice of motion returnable 3/31/78, with memo of law and affidavits of H. Lowenkron, S. Baron and M. Altin for a preliminary injunction, filed.
	***
4/13/80	Answer of defendant Premo Pharmaceutical Labs Inc. ("Premo") filed.
	***
5/1/78	Answer of Inwood Laboratories, Inc. ("Inwood"), filed.
	***
5/11/78	Plaintiff's reply to Counterclaim of Darby Drug Co. Inc. ("Darby").
5/15/78	By NICKERSON J. — FINAL DECREE BY CONSENT permanently enjoining LOWITT LABS, INC. from passing off of or substituting cyclandelate capsules from another source as and for plaintiff's CYCLOSPASMOL, etc. See decree.

Relevant Docket Entries

***

Affidavit of Seymour Blackman filed.

Affidavit of Edward Stempel filed.

***

5/16/78 ANSWER and amended complaint of defendants Darby, MD Pharmaceutical Company ("MD"), Rugby Laboratories, Inc. ("Rugby") and Sherry Pharmaceutical Co. ("Sherry"), filed.

Affidavits of Joseph Ashkin, Kent D. Shinbach, and memo of law in opposition to plaintiff's motion for a preliminary injunction, filed.

***

Affidavit in opposition to motion for a preliminary injunction filed with memo.

***

5/19/78 Affidavits of Steven J. Baron, Jay Draper, Richard C. Johnston and Bernard L. Sparta filed.

***

6/6/78 Reply of plaintiff to counterclaim in amended answer of Darby, Sherry, Rugby and MD.

Relevant Docket Entries

Deposition transcript of Inwood filed.

Deposition transcript of Premo filed.

Deposition transcript of Darby, Rugby and Sherry filed.

***

Plaintiff's reply affidavits filed.

***

6/28/78 Second affidavit of Seymour N. Blackman submitted on behalf of defendant Premo in opposition to plaintiff's motion for preliminary injunction, filed.

***

8/02/78 By NICKERSON J. — Memorandum and Order dated 8/2/78, plaintiff's motion for a preliminary injunction are not warranted (see order; copies mailed), filed.

***

8/18/78 By NICKERSON J. — Order denying plaintiff's motion for a preliminary injunction except as to the use of the word CYCLOSPASMOL, etc., filed.

***

Relevant Docket Entries

9/13/78	Notice of appeal filed by plaintiff, filed, copies mailed.
	***
10/06/78	Record on appeal, certified and mailed to Court of Appeals.
	***
7/05/79	Certified copy of mandate received and filed from Court of Appeals affirming decision of District Court, and taxing costs as indicated.
	***
1/15/80	Before NICKERSON J. — Case called. Counsel for both sides present. Trial — Jan. 21 at 9:30 a.m.
	***
1/21/80	Before NICKERSON J. — Case called. Trial ordered & begun. Trial continued to 1/22/80.
1/22/80	Before NICKERSON J. — Case called. Trial resumed. Trial continued to 1/23/80.
1/23/80	Before NICKERSON J. — Case called. Trial resumed. Trial continued to 1/24/80.
1/24/80	Before NICKERSON J. — Case called. Trial resumed. Trial continued to 1/25/80.

Relevant Docket Entries

1/25/80	Before NICKERSON J. — Case called. Trial resumed. Trial continued to 1/28/80.
1/28/80	Before NICKERSON J. — Case called. Trial resumed. Trial continued to 1/29/80.
1/29/80	Before NICKERSON J. — Case called. Trial resumed. Trial continued to 1/30/80.
1/30/80	Before NICKERSON J. — Case called. Trial resumed. Trial concluded. Parties each move for Judgment. Decision reserved. Brief 2/19/80 — Reply 2/29/80.

***

1/31/80	Pretrial Order, filed.
	Stenographer's transcript dated 1/29/80 filed.
	Stenographer's transcript dated 1/30/80 filed.
2/06/80	Stenographer's transcript dated 1/28/80 filed.
2/08/80	Stenographer's transcript dated 1/25/80 filed.
	Stenographer's transcripts dated 1/21/80, 1/22/80, 1/23/80 & 1/24/80 filed.
2/20/80	By NICKERSON J. — MODIFICATION TO PRETRIAL ORDER dated 2/19/80 as follows: "27. Premo, Inwood & MD are manufacturers that sell cyclandelate capsules principally to

wholesalers, hospitals & retail pharmacies. Premo is a manufacturer that sells cyclandelate capsules principally to wholesalers and hospitals," filed.

***

4/15/80 By NICKERSON J. — Memorandum and Order dated 4/15/80 that the foregoing constitutes the Court's findings of fact and conclusions of law (see Memo & Order). Plaintiff may have judgment permanently enjoining Sherry from using the word "SPASMOL." Otherwise the complaint is dismissed. Filed (copies of this Memo & Order served upon the parties as directed).

***

4/29/80 By NICKERSON J. — JUDGMENT dated 4/28/80 that defendant Sherry is permanently enjoined from directly or indirectly using as a trademark or trade name or component the word "CYCLOSPASMOL" (see Order for details), filed.

***

5/15/80 Notice of Appeal, filed. Copy of Notice & Docket Entries sent to Court of Appeals. Attys. notified.

5/23/80 Corrections to Ives' trial transcript filed.

Relevant Docket Entries

***

6/12/80	Record on Appeal certified and mailed to the Court of Appeals with certified copies of docket entries.
6/16/80	Acknowledgment of receipt on record on appeal dated 6/13/80, filed.
8/11/80	Supplemental Record on Appeal certified and mailed to the Court of Appeals with certified copies of docket entries.

***

8/26/80	Supplemental record #2 submitting plaintiff's exhibits and one defendant's exhibit certified and handed to DAVID STIMSON for delivery to the Court of Appeals, with certified copy of docket entries.
9/08/80	Acknowledgment of receipt of record on appeal from Court of Appeals dated 9/4/80, filed.
3/10/81	Certified copy of mandate from the Court of Appeals that the judgment of the District Court is REVERSED and the action is remanded to said District Court for further proceedings in accordance with the opinion of this Court with costs to be taxed against the appellees. Filed (case reopened and reassigned to Costantino, J. by random selection).

Relevant Docket Entries

3/20/81 Record on Appeal received from Court of Appeals, acknowledgement mailed.

***

3/30/81 Plaintiff's notice of motion returnable 4/14/81 at 10:00 a.m. for an order of judgment permanently enjoining the defts from selling prescrip. drugs cyclandelate in capsules that are similar in appearance to the capsules in which plaintiff's CYCLOSPASMOL capsules are sold, filed.

4/02/81 Before Costantino, J. — Case called. Counsel for all sides present. Motion for reassignment of this case to J. Nickerson argued. Motion granted. Order to be prepared by Court.

4/13/81 Notice of motion returnable 4/14/81 at 10:00 a.m. for Judgment on the Mandate, filed.

***

5/15/81 By NICKERSON J. -- Memo dated 5/12/81, filed. Party notified.

By NICKERSON J. — Order dated 5/12/81 that defendants Darby, Inwood, MD, Premo, Rugby and Sherry, etc. are permanently restrained and enjoined from mfg. for sale, selling, offering for sale, advertising or promoting the drug cyclandelate in capsules confusingly similar to plaintiff's present CYCLOSPASMOL capsules by reason of their blue or blue-and-red colors and their size and shape, etc., filed. Clerk to serve

	parties with copies of this Order. Parties served as directed.

***

10/16/81	Before NICKERSON J. — Case called. Defendant's motion for a stay argued. Stay on injunction denied. Plaintiff consents to stay on further proceedings.

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK — PLAINTIFF'S COMPLAINT FILED FEBRUARY 28, 1978

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK

Civil Action No. 78 C 372 (EHN)

IVES LABORATORIES, INC.

Plaintiff,

v.

DARBY DRUG CO., INC., INWOOD LABORATORIES INCORPORATED, LOWITT LABS., INC., MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.

Defendants.

COMPLAINT FOR TRADEMARK INFRINGEMENT AND UNFAIR COMPETITION

1. Plaintiff, Ives Laboratories, Inc., is a corporation organized and existing under the laws of the State of New York with its principal place of business at 685 Third Avenue, City, County and State of New York 10017.

2. Upon information and belief, Darby Drug Co., Inc. ("Darby"), is a New York corporation with a place of business at 100 Banks Avenue, Rockville Center, County of Nassau, New York 11570.

3. Upon information and belief, Inwood Laboratories Incorporated ("Inwood"), is a New York corporation with a place of business at 300 Prospect Street, Town of Hempstead, County of Nassau, Inwood, New York 11696.

4. Upon information and belief, Lowitt Labs., Inc. ("Lowitt"), is a New York corporation with a place of business at 68-19 Rockaway Bench Boulevard, Queens, New York.

5. Upon information and belief, MD Pharmaceutical Company, Inc. ("MD"), is a California corporation with a place of business at 3501 W. Cary Avenue, Santa Ana, California 92704.

6. Upon information and belief, Premo Pharmaceutical Laboratories, Inc. ("Premo"), is a New York corporation with a place of business at South Hackensack, New Jersey.

7. Upon information and belief, Rugby Laboratories, Inc. ("Rugby"), is a New York corporation with a place of business at 100 Banks Avenue, Rockville Centre, County of Nassau, New York 11570.

8. Upon information and belief, Sherry Pharmaceutical Co., Inc. ("Sherry"), is a New York corporation with a place of business at 233 West Broadway, Inwood, Town of Hempstead, County of Nassau, New York 11696.

9. Upon information and belief, all defendants are licensed to do business and/or are doing business and/or transacting business in this judicial district.

COUNT ONE AGAINST DEFENDANT SHERRY

10. This is a civil action for (a) infringement of a trademark registered in the United States Patent and Trademark Office, (b) unfair competition in the use of a trademark confusingly similar to a trademark previously used by plaintiff, (c) false designation of the origin of goods and false representation or description of goods in or affecting interstate commerce, (d) unconscionable predatory commercial practices, and (e) violation of Section 568(d), Article 24 of the New York General Business Law, of which this Court has jurisdiction under Title 15, United States Code, Sections 1121 and 1125(a); and under Title 28, United States Code, Sections 1338(a) and 1338(b). Jurisdiction additionally arises under United States Code, Title 28, Section 1332, in that this is an action between citizens of different states in which the matter in controversy exceeds, exclusive of interest and costs the sum or value of ten thousand ($10,000) dollars.

11. Since at least 1958 and long prior to the acts of the defendants, complained of herein, plaintiff, which term includes its predecessors in business and title, has been and now is manufacturing, advertising, offering for sale and selling in interstate commerce the prescription drug 3,5,5 trimethyleyclohexyl mandelate thereinafter identified by its generic name "cyclandelate") which is an orally acting peripheral vasodilator, and long prior to the acts complained of herein said preparation has been sold and is now being offered for sale by plaintiff in interstate commerce and in the State of New York, including this judicial district.

12. Continually, since long prior to the acts of the defendants, complained of herein, plaintiff has marketed such cyclandelate in capsule form — a 200 mg. pale blue capsule under the trademark CYCLOSPASMOL and a 400 mg. pale

blue/red capsule under the trademark CYCLOSPASMOL. A photograph of each of said capsules is annexed hereto as Exhibit A, and a bottle label for each of said two dosage forms bearing the trademark CYCLOSPASMOL is annexed as Exhibit B-1 and B-2.

13. Since about 1962, when interstate distribution of plaintiff's capsules first commenced, as aforesaid, both dosage forms of said drug have been marketed in compliance with the laws of the United States and of the various states and with the approval of the U.S. Food and Drug Administration.

14. Upon the introduction of plaintiff's cyclandelate vasodilator product upon the market, and continuously thereafter, it became and now is widely known and recognized by the said trademark CYCLOSPASMOL, and said trademark CYCLOSPASMOL is closely and universally associated with said product as means by which it has become known to physician's, the pharmaceutical trade and patients and its origin identified.

15. The trademark CYCLOSPASMOL is duly registered in the United States Patent and Trademark Office as follows:

Registration No.	Issued
602,919	March 8, 1955 (renewal 1975)

Said registration is now outstanding, validly subsisting, incontestable and uncancelled and plaintiff is the owner thereof. A copy of said registration is annexed hereto as plaintiff's Exhibit C.

16. Since long prior to the acts of the defendants complained of herein, plaintiff's CYCLOSPASMOL vasodilator product is and continues to be among the best known and most widely prescribed products in its field. From 1967 through 1976, alone, plaintiff has marketed throughout the United States and has sold (at wholesale value) in excess of seventy million dollars ($70,000,000) of its CYCLOSPASMOL vasodilator products.

17. Since long prior to the acts of the defendants, complained of herein, plaintiff's CYCLOSPASMOL vasodilator products have been extensively advertised and promoted on a nation-wide basis, and plaintiff has invested substantial amounts of time, effort and other resources in bringing to the attention of the medical profession the excellent quality and therapeutic characteristics of such products.

18. By reason of the extensive sales, advertising and promotion of plaintiff's CYCLOSPASMOL vasodilator products and the excellent quality of such products, plaintiff enjoys and has long enjoyed an exceedingly valuable good will in that trademark among physicians, the pharmaceutical trade and patients.

19. Continuously, since in or about 1962, plaintiff has identified its CYCLOSPASMOL cyclandelate capsules in their most widely prescribed strength (200 mg.) by means of a distinctive pale blue capsule dress.

20. Continuously, since about 1975, when plaintiff first introduced its 400 mg. dose of CYCLOSPASMOL cyclandelate capsules, plaintiff has identified such capsules by means of a distinctive capsule dress whereby half of the capsule is colored red and the other half is colored pale blue.

21. The aforesaid trade dress of said capsules, namely the pale blue color of the 200 mg. capsule and the pale blue/red 400 mg. capsule, are arbitrary and non-functional and are intended to identify the respective products of plaintiff to physicians, pharmacists and to patients.

22. Since long prior to the acts of the defendants, complained of herein, the aforesaid cyclandelate products of plaintiff have long been and are now extensively advertised and promoted on a nation-wide basis to physicians and to the pharmaceutical trade. Such advertising and promotional activity has been for the purpose of acquainting physicians with the high quality and therapeutic characteristics of plaintiff's cyclandelate products so that the physician may with full knowledge and confidence prescribe plaintiff's CYCLOSPASMOL, vasodilator to his patients. The aforesaid arbitrary, non-functional and distinctive trade dress of plaintiff's cyclandelate products are among the best known of all trade dresses in the field of vasodilator drugs and as a result thereof, plaintiff's CYCLOSPASMOL products are well known by their distinctive trade dress and have come to be and are recognized as indicia of origin with plaintiff, and patients have come to rely upon said distinctive trade dress as an indication that they are receiving the product of plaintiff which has been prescribed for them by their physician.

23. By reason of the quality and effectiveness of plaintiff's cyclandelate products, and as a result of the long continued and extensive sale, advertising and promotion of said products and their aforesaid arbitrary, non-functional and distinctive trade dress, plaintiff's cyclandelate products now enjoy and have long enjoyed an exceedingly valuable good will among physicians, the pharmaceutical trade and patients, which good will has been and

is of great value to plaintiff in the conduct of its business, and which good will is symbolized by the aforesaid arbitrary, non-functional and distinctive trade dress of said cyclandelate products.

24. Upon information and belief, with full knowledge of the distinctiveness and widespread recognition of plaintiff's trademark CYCLOSPASMOL, defendant Sherry is advertising, promoting and selling in the State of New York, including within this judicial district and in interstate commerce, cyclandelate as a vasodilator under the trademark SPASMOL which is a colorable imitation of plaintiff's trademark CYCLOSPASMOL. A photocopy of page 11, from defendant Sherry's 1977 catalog offering for sale cyclandelate under the trademark SPASMOL, is annexed as Exhibit D.

25. Upon information and belief, defendant Sherry has simulated plaintiff's trademark CYCLOSPASMOL with intent to deceive customers, to appropriate plaintiff's good will and to divert unfairly to defendant Sherry trade which would otherwise have come to plaintiff.

26. The trademark SPASMOL is a colorable imitation of CYCLOSPASMOL and its use by defendant Sherry for a cyclandelate vasodilator product is likely to cause confusion, mistake or to deceive purchasers and is an infringement of plaintiff's trademark CYCLOSPASMOL as applied to a cyclandelate product.

27. Defendant Sherry's use of the trademark SPASMOL is made without the consent of plaintiff to the detriment of plaintiff's interstate and local trade in its cyclandelate products.

28. Upon information and belief, the trademark SPASMOL used by defendant Sherry is calculated to cause confusion, mistake or deceive and has actually confused and deceived the purchasing public into believing that defendant Sherry's cyclandelate product is plaintiff's CYCLOSPASMOL cyclandelate product or a product originating with plaintiff or sponsored or associated with plaintiff.

29. Defendant Sherry's use of the trademark SPASMOL for its cyclandelate product is likely, when applied to the goods of defendant Sherry, to cause confusion or mistaken identity or to deceive purchasers into the belief that such products are the products of plaintiff or that defendant Sherry and its products are endorsed by plaintiff or are sponsored by plaintiff, and defendant Sherry's use of said trademark SPASMOL constitutes unfair competition by defendant Sherry with plaintiff.

30. The defendant Sherry has willfully and knowingly performed and continues to perform the aforesaid acts which infringe upon plaintiff's common law and statutory trademark rights, constitute unfair competition with the plaintiff, and have caused, and if not terminated, will continue to cause irreparable damage and injury to plaintiff's business, good will and reputation and plaintiff is without an adequate remedy at law.

COUNT TWO AGAINST DEFENDANTS DARBY, INWOOD, MD, PREMO, RUGBY AND SHERRY

31. Plaintiff repeats and realleges paragraphs 1 through 29, hereinabove, as though fully alleged herein.

32. Defendants Darby, Inwood, MD, Premo, Rugby and Sherry have deliberately embarked upon a course of conduct

which is deceptive, illegal and unfair and which has as its purpose and effect to compete unfairly with plaintiff in the sale of cyclandelate capsules of the same distinctive trade dress as plaintiff's cyclandelate capsules and to cause plaintiff competitive injury.

33. Said defendants Darby, Inwood, MD, Premo, Rugby and Sherry have sold and sell in the State of New York, including within this judicial district and in interstate commerce, prescription drugs, the active ingredient of which is cyclandelate, in both 200 mg. and 400 mg. capsule dosage forms. The aforesaid 200 mg. cyclandelate capsules sold by Darby, Rugby and Sherry have been and/or are being manufactured by Inwood, MD and Premo and sold by each of them, either directly to retailers or to wholesalers such as Darby, Rugby and/or Sherry and/or purchased by Sherry from Darby, Rugby and/or other wholesalers, are a pale blue color, and deceptively simulate the trade dress of plaintiff's aforesaid 200 mg. pale blue CYCLOSPASMOL cyclandelate capsules, and the aforesaid 400 mg. cyclandelate capsules which are manufactured by Inwood and Premo and sold by each of them, either directly to retailers or to wholesalers such as Darby, Rugby and/or Sherry and/or purchased by Sherry from Darby, Rugby and/or other wholesalers, are one half pale blue and the other red and deceptively simulate the trade dress of plaintiff's aforesaid 400 mg. blue/red CYCLOSPASMOL cyclandelate capsules. A photograph displaying plaintiff's 200 mg. and 400 mg. cyclandelate capsules and said defendants' 200 mg. and 400 mg. cyclandelate capsules is attached hereto as Exhibit E.

34. Both dosage forms of the aforesaid cyclandelate capsules of defendants Darby, Inwood, MD, Premo, Rugby and Sherry are being marketed in interstate commerce without

approval of the U.S. Food and Drug Administration (FDA), in violation of Title 21, United States Code, Section 355(a).

35. Said defendants Darby, Inwood, MD, Premo, Rugby and Sherry could have used, had they chosen so to do, other colors and configurations for their cyclandelate products rather than deliberately adopt the trade dress used by plaintiff and the appearance of said defendants' products so deceptively simulate the arbitrary, non-functional and distinctive trade dress of plaintiff's cyclandelate products as to be likely to cause confusion, or to cause mistake, or to deceive.

36. By their manufacture and/or sale of said cyclandelate capsules slavishly imitative of the trade dress of the aforesaid cyclandelate capsules of plaintiff, defendants Darby, Inwood, MD, Premo, Rugby and Sherry have willfully and deliberately engaged in a scheme and course of conduct to place into the hands of the pharmaceutical trade an instrument of fraud whereby cyclandelate drug preparations, not having their source with plaintiff, which are intended to be, can be, and will be passed or palmed off and substituted to the patient as and for the products of plaintiff.

37. The acts of passing off and trademark infringement by defendant Lowitt are being aided and induced by defendants Darby, Inwood, MD, Premo, Rugby and Sherry's manufacture and/or sale of cyclandelate capsules that deceptively imitate the trade dress of plaintiff's 200 mg. and 400 mg. cyclandelate capsules.

38. By their said acts complained of, defendants Darby, Inwood, MD, Premo, Rugby and Sherry have completed unfairly with plaintiff and unfairly traded upon plaintiff's good will and reputation.

39. The aforesaid acts of unfair competition of defendants Darby, Inwood, MD, Premo, Rugby and Sherry have been without the consent of plaintiff and to the detriment of plaintiff's good will in interstate and local trade.

40. The acts of defendants Darby, Inwood, MD, Premo, Rugby and Sherry, as aforesaid, have damaged plaintiff irreparably, and if not terminated, will continue to cause irreparable damage and injury to plaintiff's business, good will and reputation and plaintiff is without an adequate remedy at law.

COUNT THREE AGAINST DEFENDANTS DARBY, INWOOD, MD, PREMO, RUGBY AND SHERRY

41. Plaintiff repeats and realleges paragraphs 1 through 3, 5 through 29 and 31 through 38, hereinabove, as though fully alleged herein.

42. Defendants Darby, Inwood, MD, Premo, Rugby and Sherry have advertised, represented, and/or caused or encouraged each other and others to advertise and represent, that their 200 mg. cyclandelate capsules are comparable or equivalent to plaintiff's 200 mg. CYCLOSPASMOL cyclandelate capsules and that their 400 mg. cyclandelate capsules are comparable or equivalent to plaintiff's 400 mg. CYCLOSPASMOL cyclandelate capsules.

43. As hereinabove alleged, the 200 mg. cyclandelate capsules of defendants Darby, Inwood, MD, Premo, Rugby and Sherry are not comparable or equivalent to plaintiff's 200 mg. CYCLOSPASMOL cyclandelate capsules and the 400 mg. cyclandelate capsules of said defendants are not comparable or

equivalent to plaintiff's 400 mg. CYCLOSPASMOL cyclandelate capsules.

44. The aforesaid advertisements and representations of defendants Darby, Inwood, MD, Premo, Rugby and Sherry constitute false representations used in connection with their 200 mg. and 400 mg. capsules within the meaning of Title 15, United States Code, Section 1125(a).

45. Defendants Darby, Inwood, MD, Premo, Rugby and Sherry, with knowledge of the falsity of the aforesaid representations used in connection with said goods, have caused such goods to be transported or used in commerce in violation of said Section 1125(a) of Title 15, United States Code.

46. The acts of defendants Darby, Inwood, MD, Premo, Rugby and Sherry, as aforesaid, have damaged plaintiff irreparably, and if not terminated, will continue to cause irreparable damage and injury to plaintiff's business, good will and reputation and plaintiff is without an adequate remedy at law.

COUNT FOUR AGAINST DEFENDANT LOWITT

47. Plaintiff repeats and realleges paragraphs 1 through 4, 9 through 29 and 31 through 38, hereinabove, as though fully alleged herein.

48. A written prescription for CYCLOSPASMOL capsules was presented to Lowitt Labs, Inc., a retail pharmacy located at 69-19 Rockaway Beach Blvd., Queens, New York. Defendant Lowitt failed to fill the written prescription with CYCLOSPASMOL, passing off and substituting instead generic

cyclandelate capsules, although, labelling such prescription bottle CYCLOSPASMOL, said generic cyclandelate capsules simulating the trade dress of plaintiff's CYCLOSPASMOL capsules.

49. Defendant Lowitt's aforesaid acts constitutes trademark infringement and unfair competition with plaintiff.

50. By the aforesaid acts, defendant Lowitt has competed unfairly with plaintiff and unfairly traded upon plaintiff's good will and reputation.

51. Defendant Lowitt's aforesaid acts of trademark infringement and unfair competition are and have been without the consent or license of plaintiff and to the detriment of plaintiff's goodwill in interstate and local trade.

52. By the aforesaid acts, defendant Lowitt has damaged plaintiff irreparably, and if not terminated, will continue to cause irreparable damage and injury to plaintiff's business and goodwill, and plaintiff is without an adequate remedy at law.

COUNT FIVE AGAINST ALL DEFENDANTS

53. Plaintiff repeats and realleges paragraphs 1 through 29, 31 through 38, 42 through 45 and 48 through 50, inclusive hereinabove as though fully alleged herein.

54. Defendants' aforesaid acts complained of are all in violation of Section 368(d), Article 24 of the New York General Business Law.

55. Defendants' acts, as aforesaid, have damaged plaintiff irreparably, and if not terminated, will continue to cause

irreparable damage and injury to plaintiff's business good will and reputation and plaintiff is without an adequate remedy at law.

WHEREFORE, plaintiff prays for judgment as follows:

A. That defendants and their officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them or any of them in holding by, through or under them or acting under the authority of or in privity with them, and each and all of them, be preliminarily and permanently enjoined from directly or indirectly:

(i) using the word SPASMOL or any colorable imitation thereof, whether alone or together with other terms, in connection with the sale of pharmaceutical preparations;

(ii) printing, publishing, distributing, displaying, offering for sale, or advertising, or in any other way using for the purpose of selling or advertising pharmaceutical preparations, the word SPASMOL or any colorable imitation thereof, whether alone or together with other terms or designs;

(iii) using the word SPASMOL or any word or trademark confusingly similar thereto, in any manner which has or may reasonably have the effect of injuring plaintiff's business reputation or of diluting plaintiff's trademark.

(iv) manufacturing, distributing, advertising, promoting, offering for sale or selling cyclandelate containing products which in appearance colorably imitate or deceptively simulate the arbitrary, non-functional and distinctive appearance of plaintiff's cyclandelate products; and

(v) continuing the acts of unfair competition, false representations and unconscionable predatory commercial practices herein complained of, or from otherwise competing unfairly with plaintiff, or from doing any acts that may cause the cyclandelate products of defendants Darby, Inwood, MD, Premo, Rugby and Sherry to be mistaken for or confused with or substituted for or passed off as plaintiff's cyclandelate products and/or aiding or inducing others to commit any of the foregoing.

B. That defendants be required to deliver up to this Court for destruction: (i) all existing stocks in their possession or under their control, and lots which can be recalled or recovered from the trade of cyclandelate products having an appearance which is similar to the arbitrary, non-functional and distinctive appearance of plaintiff's cyclandelate products, (ii) all packages, package inserts, labels, labelling, and any other written or printed materials in their posession or under their control which display or show capsules the appearance and configurations of which are similar to the arbitrary, non-functional and distinctive appearance of plaintiff's cyclandelate capsules, or which bear the statements "comparable to CYCLOSPASMOL", "equivalent" or any statements of similar import that may be likely to cause confusion, or to cause mistake, or to deceive purchasers or others, and (iii) all advertising and promotional material, package inserts, labels, tags, cartons, boxes, containers, brochures, pamphlets, tear sheets, specification sheets, purchase orders, invoices, letterheads, and any other material of any type bearing the word SPASMOL, whether alone or together with other terms or designs.

C. That defendants be ordered to file with this Court and to serve upon plaintiff, within thirty (30) days after service upon defendants of the decree of injunction issued by the Court in this action, a report in writing under oath setting forth in detail the manner and form in which defendants have complied with such injunction.

D. That defendants be required to account to plaintiff for any and all profits derived by them and all damages sustained by plaintiff, by reason of the acts of infringement, unfair competition, false representations and unconscionable commercial practices, hereinabove complained of, and that the damages herein be trebled pursuant to Section 35 of the United States Trademark Act of 1946 (15 U.S.C. §1117).

E. That defendants be required to pay to plaintiff the costs and disbursements of this action including reasonable attorneys fees.

F. That plaintiff have such other and further relief as to the Court may seem just and equitable.

By Egon E. Berg
Egon E. Berg
685 Third Avenue
New York, New York 10017
(212) 986-1000 - Ext. 291

OF COUNSEL:

Vito V. Bellino
Mortimer Altin
Steven Baron

685 Third Avenue
New York, New York
Dated: February 28, 1978

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK — FINAL DECREE BY CONSENT, FILED MAY 15, 1978

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Civil Action No. 78 C 372 (EHN)

IVES LABORATORIES, INC.,

Plaintiff

vs.

DARBY DRUG CO., INC. et al.,

Defendants.

FINAL DECREE BY CONSENT

Plaintiff Ives Laboratories, Inc. having filed its complaint herein on the 28th day of February, 1978; and defendant Lowitt Labs, Inc. having appeared, and affidavits having been filed by plaintiff in support of a preliminary injunction herein, and defendants having been given an opportunity for discovery, and Lowitt Labs, Inc. having admitted performing the acts complained of against it in the complaint, and having consented to the entry of this decree; and Ives Laboratories, Inc. having moved the Court for the injunction set forth in this decree, having consented to the entry of said decree, and having waived its claim to damages against defendant Lowitt Labs, Inc.; it is therefore

ORDERED, ADJUDGED AND DECREED that the Court has jurisdiction of the subject matter herein, and of plaintiff Ives Laboratories, Inc. and defendant Lowitt Labs, Inc.; and it is further

ORDERED, ADJUDGED AND DECREED that defendant Lowitt Labs, Inc., and each and all of its officers, agents, servants, and employees, and all persons in active concert or participation with them or any of them, or holding by, through or under them or acting under the authority of or in privity with them, be permanently enjoined from passing off or substituting cyclandelate capsules from another source as and for plaintiff's CYCLOSPASMOL capsules and from using plaintiff's trademark CYCLOSPASMOL or any other name or mark so similar thereto as to be likely to cause confusion, mistake, or deception, to identify products from a source other than plaintiff; and it is further

ORDERED, ADJUDGED AND DECREED that neither party consenting to this decree shall have or recover damages or costs against each other in this action; and it is further

ORDERED, ADJUDGED AND DECREED that this decree cannot be used for advertising purposes; and it is further

ORDERED, ADJUDGED AND DECREED that this Court retains jurisdiction over defendant Lowitt Labs, Inc. to enforce the terms of this decree.

Dated: Brooklyn, New York
May 12, 1978

s/ Eugene H. Nickerson
UNITED STATES DISTRICT JUDGE

Final Decree by Consent

Plaintiff hereby consents to the issuance and entry of a final judgment herein against defendant Lowitt Labs, Inc. in the form and content as set forth above without further notice.

Dated: May 11, 1978

ROGERS HOGE & HILLS

s/ William
Attorneys for Plaintiff

Defendant Lowitt Labs, Inc. hereby consents to the issuance and entry of a final decree in form and content as set forth above without further notice.

Dated: May 10, 1978

LOWITT LABS, INC.

s/ Norman D. Lazar, pres.
Title: President

JACOBSON & GOLDBERG

s/ Arthur Goldberg
Attorneys for Lowitt Labs, Inc.
591 Stewart Avenue
Garden City, New York 11530

[Verification omitted in printing]

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK —PRETRIAL ORDER, FILED JANUARY 31, 1980

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Civil Action No. 78 C 372 (EHN)

IVES LABORATORIES, INC.,

Plaintiff

-against-

DARBY DRUG CO., INC., et al.,

Defendants.

PRETRIAL ORDER

I. Jurisdictional Basis for the Litigation:

This is an action in which plaintiff alleges that the sale by defendants of look-alike prescription drug capsules constitutes a false designation of origin or false representation in violation of Section 43(a) of the federal Trademark Act, 15 U.S.C. §1125(a); constitutes common law trademark infringement and unfair competition under the laws of the State of New York; and is a violation of New York's anti-dilution statute, General Business Law §368(d). Plaintiff also claims that the defendants are liable for trademark infringement and unfair competition, as contributory infringers, for the infringement of plaintiff's federally registered trademark CYCLOSPASMOL, pursuant to 15 U.S.C. §1114. Plaintiff, in addition, alleges that defendants are guilty of unfair competition and of a violation of Section 43(a) for representing that their generic cyclandelate is equivalent to plaintiff's CYCLOSPASMOL cyclandelate. Finally, plaintiff claims that Sherry's use of SPASMOL was an infringement of its federally registered trademark CYCLOSPASMOL.

This Court has jurisdiction of these claims pursuant to 28 U.S.C. §§1331 and 1338.

II. Stipulated Facts:

The parties, while reserving objections to their relevance or admissibility, stipulate to the following facts:

A. The Parties:

1. Plaintiff, Ives Laboratories, Inc., (hereinafter "Ives") is a corporation organized and existing under the laws of the State of New York, with its principal place of business at 685 Third Avenue, New York, New York.

2. Defendant, Darby Drug Co., Inc., (hereafter "Darby") is a corporation organized and existing under the laws of the State of New York, with a place of business at 100 Banks Avenue, Rockville Center, New York.

3. Defendant, Inwood Laboratories Incorporated, (hereafter "Inwood") is a corporation organized and existing under the laws of the State of New York, with a place of business at 300 prospect Street, Inwood, New York.

4. Defendant, MD Pharmaceutical Company, Inc., (hereafter "MD") is a corporation organized and existing under

the laws of the State of California, with a place of business at 3501 W. Gary Avenue, Santa Ana, California.

5. Defendant, Premo Pharmaceutical Laboratories, Inc., (hereafter "Premo") is a corporation organized and existing under the laws of the State of New York, with a place of business in South Hackensack, New Jersey.

6. Defendant, Rugby Laboratories, Inc., (hereafter "Rugby") is a corporation organized and existing under the laws of the State of New York, with a place of business at 100 Banks Avenue, Rockville Center, New York.

7. Defendant, Sherry Pharmaceutical Co., Inc., (hereafter "Sherry") is a corporation organized and existing under the laws of the State of New York, with a place of business at 233 West Broadway, Inwood, New York.

8. The named defendant, Lowitt Labs., Inc., having signed a consent decree wherein it admitted the acts complained of and consented to an injunction, is no longer a party to this action.

B. Plaintiff's Product:

9. Ives sells cyclandelate under the trademark CYCLOSPASMOL.

10. The CYCLOSPASMOL trademark is registered in the United States Patent and Trademark Office under Registration No. 602,919. Patent and Trademark Office records show that the registration is valid and subsisting, is incontestable, and is owned by Ives.

11. CYCLOSPASMOL cyclandelate is sold by Ives in three dosage forms:

a. 100 mg. tablet in pale orange

b. 200 mg. capsule in blue

c. 400 mg. capsule in red/blue combination

12. The active ingredient in the cyclandelate product is the subject of United States Patent No. 2,707,193. The patent expired in 1972. The patent claimed only the chemical composition of the active ingredient, and did not refer to the form in which the product was to be sold.

13. Ives obtained approval from the Food and Drug Administration of its New Drug Application covering the 200 mg. CYCLOSPASMOL cyclandelate in 1962. (Defendants Premo, Sherry, Darby, Rugby and MD object to this as irrelevant).

14. Ives obtained approval from the Food and Drug Administration of its New Drug Application covering the 400 mg. CYCLOSPASMOL cyclandelate in 1974. (Defendants Premo, Sherry, Darby, Rugby and MD object to this as irrelevant).

15. Ives has been selling CYCLOSPASMOL cyclandelate in the 200 mg. form since 1962 and in the 400 mg. form since 1975.

16. The blue and blue/red colors of the capsules are not dictated by the drug within the capsules, said drug being a white powder.

17. All CYCLOSPASMOL cyclandelate capsules sold by Ives show the name Ives and the NDC number 4148 (400 mg.) or 4124 (200 mg.).

18. CYCLOSPASMOL cyclandelate is marketed as a peripheral vasodilator product used for the treatment and management of peripheral and cerebral vascular diseases.

19. Vasodilators are maintenance drugs, used by patients over long periods of time.

20. Cyclandelate can be dispensed only by prescription.

21. Ives sells CYCLOSPASMOL cyclandelate to wholesalers, retail pharmacists, and hospitals.

22. The advertising and promotion of CYCLOSPASMOL cyclandelate is primarily to prescribing physicians and is not to the general public.

23. A large number of patients for whom peripheral vasodilators are prescribed are elderly and have diminishing visual acuity, i.e. cannot see well.

24. Employees or agents of plaintiff presented to various pharmacies prescriptions for CYCLOSPASMOL (to be dispensed as written) that were filled by the pharmacies with generic cyclandelate rather than CYCLOSPASMOL. In some instances the prescriptions, containing generic cyclandelate, were labelled CYCLOSPASMOL. Copies of the respective prescriptions and the prescription bottles as dispensed are identified in this Pretrial Order as Plaintiff's Exhibits 32(a) through (m).

25. The pharmacies referred to in paragraph 24 were selected from shops at the suggestion of employees of Ives because they thought these pharmacies might be making illegal substitutions in filling prescriptions for CYCLOSPASMOL.

C. Defendants Businesses and Products:

26. All of the defendants sell generic cyclandelate capsules.

27. Premo, Inwood and MD are manufacturers that sell cyclandelate capsules principally to wholesalers, hospitals and retail pharmacies.

28. Defendant Premo first offered for sale and sold its blue 200 mg. cyclandelate capsule and its blue/red 400 mg. cyclandelate capsule in 1976.

29. Inwood first offered for sale and sold its 200 mg. cyclandelate capsule and its 400 mg. cyclandelate capsule in June of 1976.

30. Darby, Rugby, and Sherry are wholesalers that purchase cyclandelate capsules and resell them primarily to physicians and retail pharmacies.

31. All of the defendants except MD sell cyclandelate in two dosage forms, a 200 mg. capsule which is blue and a 400 mg. capsule which is blue/red. MD sells only the 200 mg. in a blue capsule.

32. The colors of the defendants' cyclandelate capsules are identical to the blue and blue/red colors used by plaintiff.

33. At the commencement of this litigation, all of the defendants sold cyclandelate capsules bearing no imprint. Premo began to use the word Premo on its capsules in or about July 1978, after commencement of this suit. On or about July 26, 1979, Inwood imprinted NDC #258 on its 400 mg. cyclandelate capsule, and on or about August 6, 1979, Inwood imprinted NDC 258 on its 200 mg. cyclandelate capsule.

34. The copying of the colors of plaintiff's CYCLOSPASMOL cyclandelate capsules by the defendant manufacturers was intentional.

35. Defendants' respective names are on the labels of bottles of cyclandelate capsules emanating from each of them.

36. It is not the practice of pharmacists to dispense prescription capsules, including cyclandelate capsules, in their original bottles. Pharmacists rebottle such capsules when filling prescriptions, and apply their own labels to those bottles.

37. The defendants have done no clinical investigations or clinical testing in connection with the cyclandelate products sold by them. (This has been ojected to as irrelevant).

38. Plaintiff will not claim in this litigation that the cyclandelate sold by the defendants does not contain the same active ingredient as the CYCLOSPASMOL cyclandelate sold by the plaintiff.

39. Sherry has used SPASMOL as a trademark for the cyclandelate distributed by it. Although Sherry had already ceased use of that trademark, this Court entered a preliminary injunction against use of SPASMOL pending final determination of this suit.

D. Regulatory Agencies:

40. There are published in the May 25, 1979 issue of the Federal Register a notice of a proposal by the Food and Drug Administration to withdraw approval of new drug applications for all peripheral vasodilators. Cyclandelate is one of several products to which the notice applies. (This has been objected to as irrelevant by all defendants except Inwood).

41. Ives has filed a Request for Hearing with the FDA in connection with the above-identified notice. (This has been objected to as irrelevant).

42. Premo has filed a Request for Hearing with the FDA in connection with the above-identified notice. Its request relates to several vasodilators now sold by Premo, or which Premo contemplates selling in the future, including isoxuprine hydrochloride, cyclandelate, tolazoline hydrochloride, nicotinyl alcohol and nylidrin hydrochloride. (This has been objected to as irrelevant).

43. The National Association of Pharmaceutical Manufacturers ("NAPM"), on behalf of its members, which includes the defendants, filed a Request for Hearing regarding the above-identified notice. Its request relates to several vasodilators now sold by NAPM's members, and which NAPM's members contemplate selling in the future, including isoxuprine hydrochloride, cyclandelate, totazoline hydrochloride, nicotinyl alcohol and nylidrin hydrochloride. (This has been objected to as irrelevant by all defendants except Inwood).

III. Exhibits to be Offered in Evidence:

A. Plaintiff's Exhibits:

1. United States Patent No. 2,707,193 for cyclandelate.

2. Cyclandelate powder.

3. Specimen gelatine capsules.

4. CYCLOSPASMOL 100 mg. tablets.

5. Parke-Davis industrial products color wheel.

6. Scherer Hardshell Capselector. (Reserve right to object).

7. Box and bottle of CYCLOSPASMOL, 200 mg.

8. Box and bottle of CYCLOSPASMOL, 400 mg.

9. Examples of Promotional Material for CYCLOSPASMOL cyclandelate distributed by Ives. (Reserve right to object).

10. Examples of advertising in professional journals for CYCLOSPASMOL cyclandelate.

11. Blister pack of five individual capsules of CYCLOSPASMOL, 200 mg. (Object without foundation).

12. Blister pack of five individual capsules of CYCLOSPASMOL, 400 mg. (Object without foundation).

13. Physician's sample of box and bottle of CYCLOSPASMOL, 200 mg. (Object without foundation).

14. Physician's sample of box and bottle of CYCLOSPASMOL, 400 mg. (Object without foundation).

15. Samples of Inwood laboratories, Inc. cyclandelate, 200 mg. (Inwood reserves the right to object to Exhibits 15 and 16 unless such samples bear Inwood's NDC imprint).

16. Samples of Inwood Laboratories, Inc. cyclandelate, 400 mg. (Inwood reserves the right to object to Exhibits 15 and 16 unless such samples bear Inwood's NDC imprint).

17. Samples of MD Pharmaceutical Co., Inc. cyclandelate, 200 mg.

18. Samples of Premo Pharmaceutical Laboratories, Inc. cyclandelate, 200 mg.

19. Samples of Premo Pharmaceutical Laboratories, Inc. cyclandelate, 400 mg.

20. Bottle of Rugby Laboratories, Inc. cyclandelate, 200 mg.

21. Bottle of Rugby Laboratories, Inc. cyclandelate, 400 mg.

22. Bottle of Darby cyclandelate, 200 mg.

23. Bottle of Darby cyclandelate, 400 mg.

24. Bottle of Sherry cyclandelate, 200 mg.

25. Bottle of Sherry cyclandelate, 400 mg.

26. Specimens of Premo price lists and product sheets.

27. Specimens of Inwood price lists and product sheets.

28. Catalogues of Sherry, Darby and Rugby.

29. Bottle of CYDEL cyclandelate, 200 mg.

30. Bottle of CYCLANFOR cyclandelate, 400 mg.

31. Bottle of CYCLANFOR cyclandelate, 200 mg.

32. Prescription Bottles and prescriptions:

    a. Dispensed prescription bottle, Lowitt Labs, Inc., "1-25-78".

    b. Dispensed prescription bottle, Tylertown Drug Store "Cyclospasmol 200 mg 2-16-78".

c. Dispensed prescription bottle, Pickwich Pharmacy “Cyclospasmol 200 mg. 3-15-78”.

d. Dispensed prescription bottle, Pickwick Pharmacy “Cyclospasmol 400 mg. 3-22-78”.

e. Dispensed prescription bottle, Pickwick Pharmacy “Cyclospasmol 200 mg. 3-15-78”.

f. Dispensed prescription bottle, Merill Pharmacy “Cyclospasmol 200 mg. 3-22-78”.

g. Dispensed prescription bottle, Civic Drug Center “Cyclospasmol 400 mg. 3-27-78”.

h. Dispensed prescription bottle, Carylsle pharmacy “Cyclospasmol 400 mg. 4-24-78”.

i. Dispensed prescription bottle, Sentry Drugs, Taylor, Michigan “Cyclospasmol 400 mg. 4-24-78”.

j. Dispensed prescription bottle, Sentry Drugs, Southfield, Michigan “Cyclospasmol 400 mg. 4-25-78”.

k. Dispensed prescription bottle, Carlysle Pharmacy “Cyclospasmol 200 mg. 4-27-78”.

l. Dispensed prescription bottle, Sentry Drugs, Taylor, Michigan "Cyclospasmol 200 mg. 4-27-78".

m. Dispensed prescription bottle, Sentry Drugs, Southfield, Michigan "Cyclospasmol 200 mg. 4-27-78".

34. Bottle containing capsules for use in physicians' interview. (Reserve right to object).

35. Bottles containing capsules for use in patient interview re 200 mg. cyclandelate. (Reserve right to object).

36. Bottles containing capsules for use in patient interview re 400 mg. cyclandelate. (Reserve right to object).

37. Specimen questionnaire for physicians. (Reserve right to object).

38. Specimen questionnaire for patients. (Reserve right to object.).

39. Instructions to interviewers. (Reserve right to object).

40. Analysis of survey results, and back-up material. (Reserve right to object).

41. Completed questionnaires, with the names of patients and physicians masked. (Reserve right to object).

42. List of physicians who are believed to prescribe CYCLOSPASMOL. (Reserve right to object).

43. Instructions to Ives detail men re identity of physicians and pharmacies. (Reserve right to object).

44. List of pharmacies in New York State that are believed to dispense both CYCLOSPASMOL and generic cyclandelate. (Reserve right to object).

45. Analysis of results of shopping in New York State. (Reserve right to object).

46. Map showing area covered by survey. (Reserve right to object).

47. Dispensed prescription bottles from the following pharmacies, with envelopes showing shoppers' records and containing receipts and copies of prescriptions: (Object unless foundation is laid).

Genaud Sidney Pharmacy (Gibson Chemical) Valley Stream, New York.
Middle Neck Pharmacy, Great Neck, New York.
Parkdale Pharmacy, Valley Stream, New York.
A & S Rx Center, Hempstead, New York.
Rosebank Pharmacy, Staten Island, New York.
Tri-Boro Pharmacy, Astoria, New York.
Health World Pharmacy, Flushing, New York.
Marder's (Ron-See Drugs) Laurelton, New York.
Pharmacy at Leisure Country, Ridge, New York.

Simelson's Square Pharmacy, Bronx, New York.
Miele Pharmacy, Brooklyn, New York.
Cur-Al Rx Center, Hempstead, New York.
Finast Supermarkets, Bronx, New York.
Rxcetera Drugs, Valley Stream, New York.
Genovese Rx, Shirely, New York.
Zive Pharmacy, Bronx, New York.
Drug Masters, Hempstead, New York.
Economy Drug, Williston Park, New York.
Gibson Chemist, Valley Stream, New York.
County Pharmacy, Brooklyn, New York.
Seaport Pharmacy, Port Jefferson, New York.
Vadala's Pharmacy, Highland, New York.
Rite Aid Pharmacy, Yonkers, New York.
Bronx Rx Center, Bronx, New York.
Anscott Rx, East Northport, New York.
Leff, Bronx, New York.
Nu-Era, Bronx, New York.
Genovese Drugs, Mt. Vernon, New York.
Martini's Northside Pharmacy, James Point, New York.
Leda Pharmacy, New York, New York.
Gilliar Drugs, Great Neck, New York
Birchwood Pharmacy, Bayside, New York.
Wading River Pharmacy, Wading River, New York.
Austin Drugs, Great Neck, New York.
Tick Tock Drugs, East Northport, New York
Nordale Rx, East North Port, New York.
Sloatsburg Pharmacy, Sloatsburg, New York.
Samone Pharmacy, Oyster Bay, New York.
Wykagyl Pharmacy, New Rochelle, New York.
Franconia Pharmacy, Flushing, New York.

Procita Pharmacy, West Babylon, New York.
Pound Ridge Pharmacy, Pound Ridge, New York.
The Medicine Shoppe, Northport, New York.
Grimaldi Pharmacy, Inc., Brooklyn, New York.
Long Island Prescription Center, Cedarhurst, New York.
Town Hall Pharmacy, Elmsford, New York.
Pathmark Drugs, Copaigue, New York.
Drug Mart, Bellmore, New York.
Linden Park Pharmacy, Howard Beach, New York.
Ace Pharmacy, Riverdale, New York.
Hunts Point Drug Co., Bronx, New York.
Ellvin Drugs, Hempstead, New York.
Steward Drugs, Bayside, New York.
Franhill Drugs, Hollis, New York.
Orso Drug Co., Inc., Valley Stream, New York.
Arkay, New York, New York.
Town Hall Pharmacy, Elmsford, New York.
CVS Pharmacy, Rochester, New York.
Rite Aid Pharmacy, Utica, New York.
Carl Drug Company, Auburn, New York.
Rite Aid Pharmacy, LeRoy, New York.
Oneida Square Pharmacy, Utica, New York.
Carls Drug Company, Oneonta, New York.
Loudon Pharmacy, Albany, New York.
Canton Drugs, Tonawanda, New York.
Winchell's Pharmacy, Greenwich, New York.
Webster Drugs, Bronx, New York.
Jax Leader Drugs, Rochester, New York.
Crone Supe-Rx Drugs Inc., Johnson City, New York.

Park Pharmacy, Johnson City, New York.
Wegmans Pharmacy, East Rochester, New York.
Rite Aid Pharmacy, Utica, New York.
Rite Aide Pharmacy, Syracuse, New York.
Bert A. Lies Pharmacy, Cheektowaga, New York.
Northside Apothecary, Rochester, New York.
Rite Aide Pharmacy, Utica, New York.
Beaver Pharmacy, Canisteo, New York.
Hargrave's Pharmacy, Fulton, New York.
MacFinn Drug Company, Saratoga Springs, N.Y.
Seth Drugs, Scotia, New York.
Luizzi Pharmacy, Inc., Endicott, New York.
The Parkleigh Pharmacy, Rochester, New York.
Fisk & Penning Pharmacy, Kenmore, New York.
K. Drugs, Tonawanda, New York.

48. Curricula vitae for plaintiff's expert witnesses.

49. Premo request for hearing concerning cyclandelate filed with FDA. (Objected to as irrelevant).

50. Physicians Desk Reference, 1977 and 1979 Editions.

51. Samples of the following prescription drugs in the same dosage form, but in different colors:

    a. papaverine hydrochloride (a vasodilator).

b. amitriptyline hydrochloride (an anti-depressant).

c. chlordizaepoxide hydrochloride (tranquilizer).

52. Chart showing prescription drugs in the same dosage form, but in different colors. (Reserve right to object).

53. Specimens and labelling re change of colors of PHENERGAN product. (Object as irrelevant).

54. Records and specimens from Calvin Pharmacy. (Reserve right to object).

55. Specimen prescription bottles obtained from patients participating in survey interviews. (Object as being irrelevant and immaterial).

56. IMS material concerning frequency of prescribing of various drugs, including cyclandelate, specifically:

    a. IMS American National Prescription Aduit Therapeutic Category Report October, 1979 pp. 204, 207, 315.

    b. IMS American National Prescription Aduit Therapeutic Category Report December, 1978 pp. 197, 303, 199.

    c. National Disease and Therapeutic Index pp. (1)-(7); (13), (14); January-December

1978, pp. 901, 905; p. 276; October, 1978-September, 1979 pp. 900, 907, 1281.

57. Publication showing names of most widely prescribed drugs.

58. Catalogues from other generic manufacturers or distributors.

B. Defendants' Exhibits:

1. Premo:

1. Curriculum Vitae of Dr. Stempel.

2. Bibliography of Dr. Stempel.

3. Part III, January 1979 New York State Pharmacy Boards. (Plaintiff reserves right to object).

4. Board with look-alike drugs. (Object as to relevancy).

5. Key to Exhibit 4.

6. Prescription for Cyclospasmol. (Reserves right to object).

7. Pharmacist's label of Cyclospasmol. (Reserves right to object).

8. Prescription for cyclandelate. (Reserves right to object).

9. Pharmacist's label for cyclandelate. (Reserves right to object).

10. Premo's bottle of 200 mg. cyclandelate.

11. Premo's bottle of 400 mg. cyclandelate.

12. Curriculum Vitae of Dr. Bloom.

13. Apresoline 50 mg. — Ciba. (Reserves right to object).

14. Hydralazine 50 mg. — Lederle. (Reserves right to object).

15. Antivert 25 mg. — Roerig. (Reserves right to object).

16. Antivert 12.5 mg. — Roerig. (Reserves right to object).

17. Meclizine Hcl. 12.5 mg. — Lederle. (Reserves right to object).

18. Meclizine Hcl. 25 mg. — Lederle. (Reserves right to object).

19. *Physicians' Desk Reference.*

20. Schein catalog — Pre-Winter 1979.

21. Schein catalog - Winter 1979.

22. Current Premo catalog. (Reserves right to object).

23. a. Prescription for Cyclospasmol filled at East View Apothecary.*
    b. Receipt for Exhibit 23a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 23a.

24. a. Prescription for Cyclospasmol filled at Four Corners Pharmacy.
    b. Receipt for Exhibit 24a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 24a. (Objection).

25. a. Prescription for Cyclospasmol filled at Prescriptions Exclusive.
    b. Receipts for Exhibit 25a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 25a. (Objection).

26. a. Prescription for Cyclospasmol filled at Prescriptions Limited of Madison Avenue.
    b. Receipt for Exhibit 26a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 26a. (Objection).

27. a. Prescription for Cyclospasmol filled at Rite Aid Pharmacy.
    b. Receipt for Exhibit 27a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 27a. (Objection).

28. a. Prescription for Cyclospasmol filled at Barney's Prescriptions.

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* Plaintiff objects to all exhibits in 23 through 47 unless defendant Premo produces for inspection *all* prescriptions filled in the Chung shoppings.

- b. Receipt for Exhibit 28a.
- c. Cyclospasmol capsules filled in response to prescription for Exhibit 28a. (Objection).

29.
- a. Prescription for Cyclospasmol filled at Church Pharmacy.
- b. Receipt for Exhibit 29a.
- c. Cyclospasmol capsules filled in response to prescription of Exhibit 29a. (Objection).

30.
- a. Prescription for cyclospasmol filled at Dan's Grand Avenue Pharmacy.
- b. Receipt for Exhibit 30a.
- c. Cyclospasmol capsules filled in response to prescription of Exhibit 30a. (Objection).

31.
- a. Prescription for Cyclospasmol filled at Group Drug Service (Maiden Lane).
- b. Receipt for Exhibit 31a.
- c. Cyclospasmol capsules filled in response to prescription of Exhibit 31a. (Objection).

32.
- a. Prescription for Cyclospasmol filled at Sav-On Drug Store.
- b. Receipt for Exhibit 32a.
- c. Cyclospasmol capsules filled in response to prescription of Exhibit 32a. (Objection).

33.
- a. Prescription for Cyclospasmol filled at D & R Pharmacy, Inc.
- b. Receipt for Exhibit 33a.
- c. Cyclospasmol capsules filled in response to prescription of Exhibit 33a. (Objection).

34. a. Prescription for Cyclospasmol filled at Pathmark Pharmacy (Fulton St., Brooklyn).
    b. Receipt for Exhibit 34a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 34a. (Objection).

35. a. Prescription for Cyclospasmol filled at DJ Drug.
    b. Receipt for Exhibit 35a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 35a. (Objection).

36. a. Prescription for Cyclospasmol filled at Willner Drug Shop, Inc.
    b. Receipt for Exhibit 36a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 36a. (Objection).

37. a. Prescription for Cyclospasmol filled at Norwood Rexall Drugs.
    b. Receipt for Exhibit 37a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 37a. (Objection).

38. a. Prescription for Cyclospasmol filled at Group Drug Service (Beekman Street).
    b. Receipt for Exhibit 38a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 38a. (Objection).

39. a. Prescription for Cyclospasmol filled at Health Wise Pharmacy.
    b. Receipt for Exhibit 39a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 39a. (Objection).

40. a. Prescription for Cyclospasmol filled at Lipton Chemists Inc.
    b. Receipt for Exhibit 40a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 40a. (Objection).

41. a. Prescription for Cyclospasmol filled at Abraham & Straus Prescription Department.
    b. Receipt for Exhibit 41a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 41a. (Objection).

42. a. Prescription for Cyclospasmol filled at Bonus Drug Inc.
    b. Receipt for Exhibit 42a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 42a. (Objection).

43. a. Prescription for Cyclospasmol filled at Kings Pharmacy.
    b. Receipt for Exhibit 43a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 43a. (Objection).

44. a. Prescription for Cyclospasmol filled at Pathmark Pharmacy (880 Third Ave.)
    b. Receipt for Exhibit 44a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 44a. (Objection).

45. a. Prescription for Cyclospasmol filled at Greenfield, The Chemist.

- b. Receipt for Exhibit 45a.
- c. Cyclospasmol capsules filled in response to prescription of Exhibit 45a.(Objection).

46. a. Prescription for Cyclospasmol filled at BJS Drugs, Inc.
    - b. Receipt for Exhibit 46a.
    - c. Cyclospasmol capsules filled in response to prescription of Exhibit 46a. (Objection).

47. a. Prescription for Cyclospasmol filled at Prescriptions Limited of Broadway.
    - b. Receipt for Exhibit 47a.
    - c. Cyclospasmol capsules filled in response to prescription of Exhibit 47a. (Objection).

48. Premo invoice to Generix Drug Sales Co. for 200 mg. cyclandelate capsules, dated 1/7/76.

49. Premo invoice to Valley Pharmaceutical & Vit. for 400 mg. cyclandelate capsules, dated 1/7/76.

50. Curriculum Vitae of Dr. Sorensen.

51. Patient Pill Board.

2. Inwood:

1. Samples of Inwood's cyclandelate, 200 mg., bearing NDC imprint #258.

2. Samples of Inwood's cyclandelate, 400 mg., bearing NDC imprint #258.

3. Specimens of Inwood price lists and product sheets.

4. Various United States Veterans Administration specifications for various pharmaceutical products. (Objection without foundation).

5. United States Government Federal Standard for Capsules for Medicinal Purposes, dated January 7, 1977. (Objection without foundation and reserves other objection until the document has been produced).

6. Publication of the New York State Assembly's Office of Legislative Counsel entitled, "Are Generics Safe", dated June 23-24, 1978. (Objection without foundation and reserves other objection until the document has been produced and read).

7. Federal Register notices appearing in 44 F.R. 30436-37, 30443-30446 (May 28, 1979).

8. &
9. Samples of Inwood's cyclandelate, 200 m.g. & 400 m.g. bearing the "Inwood" name imprinted thereon.

10. Curriculum Vitae of Dr. Shafer

11. State of New Jersey Purchase Bureau Records 1976-77.

3. Sherry, Darby, Rugby and MD:

1. Curriculum Vitae of Dr. Taylor.

2. Curriculum Vitae of Dr. Shinbach.

3. Records of defendants Darby and Rugby as to when they began purchasing cyclandelate from manufacturers for re-sale to doctors, pharmacies and hospitals.

4. Records of defendants Darby and Rugby as to representations, guarantees and warranties made by companies which sold cyclandelate to said defendants. (Objection as to relevance).

5. Catalogues of various generic drug wholesalers. (Objection)

6. Examples of capsules to be used by Darby, Rugby and Sherry with the same Rugby imprinted thereon together with code number.

7. Records of defendants Darby and Rugby showing breakdown of sales of cyclandelate to doctors, to pharmacies and to others.

8. Letter by Dr. Taylor printed in the New England Journal of Medicine, May 18, 1978 issue.

IV. Witnesses:

The names and addresses of the witnesses, together with a brief narrative of their expected testimony, are as follows:

A. Plaintiff's Witnesses:

1. Herbert Lowenkrohn
Ives Laboratories
685 Third Avenue
New York, New York

Mr. Lowenkrohn will testify about the general nature of the Ives business and about CYCLOSPASMOL cyclandelate including extent of sales, type and extent of promotion, intended use of the product, categories of patients likely to use the product, methods of distribution, availability of colored capsules on the open market, and harm to Ives arising from the conduct of the defendants.

2. Alfred Ling, M.D., Ph. D.
Ives Laboratories
685 Third Avenue
New York, New York

Dr. Ling will testify about the extent, nature and cost of the clinical investigations on cyclandelate done by Ives for submission to the FDA.

3. Fred Bovoso
Ives Laboratories
685 Third Avenue
New York, New York

Mr. Bovoso will testify about the detailing of CYCLOSPASMOL cyclandelate to physicians, about the availability on the market of the same drugs in the same dosage form but in different colors, and about the gathering by Ives personnel of information concerning physicians prescribing and pharmacies dispensing CYCLOSPASMOL cyclandelate.

4. David Getson, M.D.
Maine Medical Center

Department of Emergency Medicine
Portland, Maine 04104

Dr. Getson will testify about procedures followed in the emergency room of a hospital in the case of drug overdose.

5. Heinz E. Lehmann, M.D.
Royal Victoria Hospital
Allan Memorial Institute
Pearl and Pine Streets
Montreal, Canada

Dr. Lehmann is a psychiatrist who will testify about his experience with patient receptivity to changes in the colors of drugs products dispensed to them.

6. Eric W. Fine, M.D.
1315 Walnut Street
Philadelphia, Pennsylvania 19107

Dr. Fine is a physician who will testify about his experience with patient receptivity to changes in the colors of drug products dispensed to them.

7. Vincent C. Desiderio, M.D.
2116 Chestnut Street
Philadelphia, Pennsylvania

Dr. Desiderio is a physician who will testify about his experience with patient receptivity to changes in the colors of products dispensed to them, and as to his practice in dispensing various colors of drug products.

8. Herbert Price
Director of Pharmacy
Nassau County Medical Center
East Meadow, New York 11554

Mr. Price will testify concerning his experience in purchasing and dispensing prescription drug products in the same dosage form, but in different colors.

9. Brendan Lawler
Trottas West Street Pharmacy, Inc.
15 Halstead Avenue
Harrison, New York 10528

Mr. Lawler will testify concerning pharmacy practice and his experience in purchasing and dispensing prescription drug products in the same dosage form, but in different colors.

10. Paul J. Smith
Wyeth Laboratories
Philadelphia, Pennsylvania

Mr. Smith will testify about the experience of Wyeth Laboratories (a division of American Home Products) when it has changed the color of a prescription drug product.

11. John M. Kashickey
Ives Laboratories
685 Third Avenue
New York, New York

Mr. Kashickey will testify about the practices followed by various governmental agencies when purchasing or seeking bids concerning drug products.

12. Dr. Benjamin Lipstein
Lipstein, Assael & Associates
333 East 57th Street
New York, New York

Dr. Lipstein will testify concerning the design of, and will analyze the results of the survey of physicians and patients. He will also testify concerning the results of shoppings done at various pharmacies in the State of New York, and about the way in which said pharmacies were selected.

13. Dr. Harry Heller
Harry Heller Research Corp.
358 Main Street
Port Washington, New York

14. Doris Lesansky
Harry Heller Research Corp.
358 Main Street
Port Washington, New York

15. Janet Bernstein
Harry Heller Research Corp.
358 Main Street
Port Washington, New York

16. Joan Milnamow
Harry Heller Research Corp.

358 Main Street
Port Washington, New York

Dr. Heller, Mrs. Lesansky, Mrs. Bernstein and Mrs. Milnamow will testify about the execution of the physician and patient surveys. In addition, plaintiff will call one field supervisor, and one interviewer, both from Syracuse, New York — Eleanor Caracca and Elise Lavalle.

17. Dr. Stephen Chappell
(or R. Lars Olson)
IMS America Ltd.
Ambler, Pennsylvania

The IMS witness will testify concerning his company's statistical back-up as to the identity of the most widely prescribed drugs and the number of physicians prescribing CYCLOSPASMOL cyclandelate in the United States.

18. Seymour Adler
2300 Olinville Avenue
New York, New York

19. Carl Kittelberger
c/o Seymour Adler

20. Sander Eisenberg
c/o Seymour Adler

21. Alfonso Paske
Lakeview Estates
918 Reed Canal Road
Daytona Beach, Florida

The above-identified witnesses, and Mr. Adler, will testify that they took prescriptions into pharmacies in New York State, had them filled, and then turned the bottles containing the prescriptions, along with a record concerning the pharmacy shop, to Dr. Lipstein or plaintiff's law firm in the same container as when purchased. Mr. Paske will testify by telephone communication if necessary.

22. Frank Whalen
Ives Laboratories
Eureka, Illinois

23. William Hastings
Ives Laboratories
Syracuse, New York

24. Kay Brady
Ives Laboratories
685 Third Avenue
New York, New York

Mr. Whalen, Mr. Hastings and Miss Brady obtained packages of generic cyclandelate labelled CYCLOSPASMOL from patients who participated in the survey interview.

25. Helen Gaucci
Ives Laboratories
685 Third Avenue
New York, New York

Miss Gaucci will testify concerning the transfer of physicians' names, addresses and telephone numbers from material furnished by detail men into computerized form. She will testify only if no stipulation can be arrived at concerning this matter.

B. Defendants Witnesses:

1. Premo:

As Presently advised, defendant Premo Pharmaceutical Laboratories, Inc. intends to call the following witnesses at trial.

1. Dr. Edward Stempel
Associate Dean
Schwartz College of Pharmacy
75 DeKalb Avenue
Brooklyn, New York 11201

Dr. Stempel is an expert in the field of pharmacy and pharmaceutical practice and will testify as to the facts contained in the affidavit he submitted herein, the manner in which certain aspects of training of pharmacy students is conducted, and pharmaceutical dispensing practices.

2. Donna Gringauz
St. John's Episcopal Hospital
327 Beach 19th Street
Far Rockaway, New York 11691

Ms. Gringauz will testify about the disadvantages of dispensing generic drug which are not look-alike of branded drugs and the advantages of standarization.

3. Martin Sperber
Vice President
Henry Schein, Inc.
5 Harbor Park Drive
Port Washington, New York 11050

Mr. Sperber will testify and give opinions as to the need for comparative advertising in selling generic drugs and the desirability of having generic look-alikes.

4. Dr. Jerry Bloom
Brookdale Hospital Medical Center
Linden Boulevard at Brookdale Plaza
Brooklyn, New York 11212

Dr. Bloom is an internist and will testify as to the desirability of having generic look-alikes and the manner in which patients use the appearance of drugs to identify their daily regimen of drug intake.

5. Mr. Douglas Chung
344 East 17th Street
Brooklyn, New York 11226

Mr. Chung is a registered pharmacist and conducted the shoppings in the New York area to ascertain whether or not illegal substitution occurs with respect to prescriptions calling for Cyclospasmol. He will also testify about his experience in identifying drugs on the basis of size, shape, and color.

6. Dr. Robert C. Sorensen
Robert C. Sorensen and Associates, Inc.

210 East 72nd Street
New York, New York 10021

Dr. Sorensen is a survey and market research expert who will testify and give opinions regarding the survey conducted by Ives.

7. John Blackman, Vice President
Premo Pharmaceutical Laboratories, Inc.
111 Leuning Street
South Hackensack, New Jersey

Mr. Blackman will testify as to Premo selling cyclandelate and the manner in which it is offered for sale.

2. Inwood

1. Seymour Field
Inwood Laboratories, Inc.
300 Prospect Street
Inwood, New York

Mr. Field will testify about the marketing practice of Inwood and the general practice of selling generic drugs with the same appearance as their brand name counterparts.

2. Dr. Nathaniel Shafer
10 East 85th Street
New York, New York 10028

Dr. Shafer is a physician who will testify about his experience with generic drugs in general, and cyclandelate specifically and his opinions with respect to the importance of marketing generic drug products in the same color as their brandname counterparts.

3. Lee Kolodny
Director of Pharmacy
Parsons Hospital
35th Avenue and Parsons Blvd.
Flushing, New York 11354

Mr. Kolodny will testify as to his experience concerning patient anxiety and nurse confusion regarding the dispensing of drugs which are a different size, shape and color than the drug previously dispensed. He will also testify as to the Pharmacy's purchasing policy of drug products including cyclandelate.

3. Sherry, Darby, Rugby and MD:

1. Joseph Ashkin
Officer and Director of Darby, Rugby and Sherry

Mr. Ashkin will testify to the general practice of selling generic drugs with the same appearance as their brand name counterparts; the use of brand names in conjunction with generic names in the catalogues of generic drug wholesale distributors; and the reasons for these common practices.

2. Kent D. Shinbach, M.D.
435 East 79th Street
New York, New York 10028

Dr. Shinbach is a psychiatrist who will testify about his experience and his opinions with respect to patient receptivity to changes in the appearance of prescription drug products dispensed to them and the value of uniformity in the appearance of equivalent drug dosage forms.

3. Judith M. Taylor, M.D.
125 Worth Street
New York, New York 10013

Dr. Taylor is a physician who will testify about her experience and her opinions with respect to patient receptivity to changes in the appearance of prescription drug products dispensed to them and the value of uniformity in the appearance of equivalent drug dosage forms.

4. Defendants Darby, Rugby, Sherry and M.D. reserve the right to present witnesses concerning the shopping and product identification surveys conducted by plaintiff, and said defendants will provide notice of such witnesses upon completion of discovery.

V. Depositions to Be Offered:

A. By Plaintiff:

1. Seymour Blackman, President of Premo.
2. Seymour Field, Vice President of Inwood.
3. Joseph Ashkin, President of Sherry, Darby and Rugby.
4. Edward Stempel.
5. Calvin Pharmacy.

6. Kent Shinbach, M.D.
7. Donna Gringauz
8. Jerry Bloom, M.D.
9. Doris Lesansky

B. By Defendants:
  1. Premo:
    1. Seymour Blackman
    2. Seymour Field
    3. Joseph Ashkin
    4. Calvin Pharmacy
  2. Inwood:
    1. Seymour Field

VI. Plaintiff's Statement of Legal and Factual Issues:

The legal issues in the case and those involving mixed questions of law and fact are as follows:

A. Does the sale of the prescription drug cyclandelate in capsules identical in color, size and shape to the CYCLOSPASMOL cyclandelate capsules sold by plaintiff constitute a false designation of origin and a false representation in violation of Section 43(a) of the Federal Trademark Act?

a. Has the appearance of the capsules acquired secondary meaning signifying origin in a single source?

b. Is the fact that the copying by defendants was intentional itself evidence of secondary meaning?

c. Can the copying be excused if defendants are able to prove that the appearance of the capsules may perform some incidental functions?

d. Is duplication of the color, size and shape of the capsules necessary in order for the defendants to compete in the sale of generic cyclandelate?

e. Can it reasonably be concluded that patients will refuse to take medication different in appearance from that previously taken?

f. Does the sale by defendants of capsules identical in color, size and shape to plaintiff's create a likelihood of confusion, mistake or deception?

g. Does the presence of markings on the capsules and the labelling on a prescription bottle which states the name of the manufacturer and/or distributor obviate the likelihood of confusion?

g. Does the fact that cyclandelate is dispensed by prescription only make irrelevant the fact that consumer patients may be confused?

B. Does the sale of the prescription drug cyclandelate in capsules identical in color, size and shape to the CYCLOSPASMOL cyclandelate capsules sold by plaintiff constitute common law trademark infringement and unfair competition under the laws of the State of New York?

a. Has generic cyclandelate been passed off by pharmacies as CYCLOSPASMOL cyclandelate?

b. Can the defendants be held liable for having placed in the stream of commerce products of an appearance that facilitates such passing off?

c. Did the defendants in their sales and promotional material also actively contribute to the aforesaid passing off?

C. Are the defendants liable as contributory infringers for infringement of plaintiff's trademark CYCLOSPASMOL by pharmacists labelling look-alike generic cyclandelate with the trademark CYCLOSPASMOL?

D. Was Sherry's trademark SPASMOL, when used to identify cyclandelate, an infringement of plaintiff's federally registered trademark CYCLOSPASMOL?

E. Is it an act of false representation under Section 43(a) of the Federal Trademark Act, and an act of unfair competition under the laws of the State of New York, for the defendants to assert that their cyclandelate products are equivalent to the prescription drug product sold by the plaintiff under the designation CYCLOSPASMOL when the defendants have done no clinical investigations to determine whether in fact their products are equivalent?

F. Have the defendants, by selling look-alike prescription drug capsules containing cyclandelate, diluted the distinctive quality inhering in the appearance of plaintiff's CYCLOSPASMOL capsules in violation of the anti-dilution statute of the State of New York, General Business Law §368(d)?

G. Is plaintiff entitled to a permanent injunction against duplication of the appearance of the capsules in which its CYCLOSPASMOL cyclandelate is sold, and to an award of damages and an accounting of defendants' profits?

H. Is plaintiff entitled to an award of reasonable attorneys' fees?

VII. Joint Statement of Defendants Darby Drug Co., Inc., MD Pharmaceutical Company, Inc., Rugby Laboratories, Inc., Sherry Pharmaceutical Co., Inc. and Premo Pharmaceutical Laboratories, Inc. As To The Legal and Factual Issues

A. Does the sale of the prescription drug cyclandelate in capsules identical in color, size and shape to Cyclospasmol cyclandelate capsules sold by plaintiff constitute a false designation of origin and a false representation in violation of Section 43(a) of the Federal Trademark Act?

B. Has plaintiff met its burden of proof that its capsules have acquired secondary meaning?

C. Does the copying of a functional aspect of a product establish secondary meaning?

D. Can there be secondary meaning to the users of the capsules in question in view of the fact that they do not select the product which is dispensed to them?

E. Does the sale of the prescription drug cyclandelate in capsules identical in color, size and shape to the Cyclospasmol cyclandelate capsules sold by plaintiff constitute common law trademark infringement and unfair competition under the laws of the State of New York?

F. If the appearance of the capsules is functional, do the defendants have the right to use that appearance in selling their capsules?

G. Can color be the subject of a perpetual monopoly or acquire secondary meaning?

H. Are the defendants liable as contributory infringers for infringement of plaintiff's trademark Cyclospasmol by pharmacists labelling look-alike generic cyclandelate with the trademark Cyclospasmol?

I. Has plaintiff met its burden of proof that it is an act of false representation under Section 43(a) of the Lanham Act and an act of unfair competition under the laws of the State of New York for the defendants to assert that their cyclandelate products are equivalent to the prescription drug product sold by plaintiff under the designation Cyclospasmol when the defendants' and plaintiff's products each contain the identical active ingredient in the same amount and plaintiff has no proof that the products lack clinical equivalency?

J. Has the plaintiff met its burden of proof under Section 368(d) of the General Business Law of the State of New York that defendants have diluted a distinctive quality in the appearance of its capsules?

K. If defendants are prohibited from selling their blue and blue-and-red cyclandelate capsules, would plaintiff be given a perpetual monopoly on cyclandelate beyond that to which it was entitled under the patent laws?

VIII. Damages:

Plaintiff submits that any determination as to the amount of damages, as to an accounting for profits, and as to an award of attorneys' fees should be made in a separate proceeding, after a determination as to the issue of liability has been made.

Dated: New York, New York

January, 1980

ACCEPTED AND AGREED TO:

ROGERS HOGE & HILLS

s/ Marie Driscoll
Attorneys for Plaintiff
90 Park Avenue
New York, New York 10016
(212) 953-9200

KIRSCHSTEIN, KIRSCHSTEIN, OTTINGER & COBRIN, P.C.

s/ Peter Cobrin
Attorneys for Defendant
Premo Pharmaceutical
Laboratories, Inc.
666 Fifth Avenue
New York, New York 10019
(212) 581-8770

SALON, BLOUSTEIN AND RAYBIN

s/ Robert V. Marrow
Attorneys for Defendants
Darby Drug Co., Inc.,
MD Pharmaceutical Company,
Inc., Rugby Pharmaceutical
Co., Inc. and Sherry
Pharmaceutical Co., Inc.
275 Madison Avenue

New York, New York 10016
(212) 532-9194

BASS, ULLMAN & LUSTIGMAN

s/ Steven R. Trost
Attorneys for Defendant
Inwood Laboratories,
Incorporated
747 Third Avenue
New York, New York 10017
(212) 751-9494

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK, MODIFICATION TO PRETRIAL ORDER, FILED FEBRUARY 20, 1980

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Civil Action No. 78 C 372 (EHN)

IVES LABORATORIES, INC.,

Plaintiff,

-against-

DARBY DRUG CO., INC., et al.,

Defendants.

MODIFICATION TO PRETRIAL ORDER

Paragraph 27 of the Pretrial Order is hereby modified so as to read as follows:

> "27. Premo, Inwood and MD are manufacturers that sell cyclandelate capsules principally to wholesalers, hospitals and retail pharmacies. Premo is a manufacturer that sells cyclandelate capsules principally to wholesalers and hospitals.

Dated: Brooklyn, New York
February 19, 1980

SO ORDERED:

s/ Eugene H. Nickerson
U.S.D.J.

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK, JUDGMENT FILED APRIL 29, 1980

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
78 C 372 (EHN)

IVES LABORATORIES, INC.,

Plaintiff,

-against-

DABRY DRUG CO., INC., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL COMPANY, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,

Defendants.

JUDGMENT

This matter having come before the Court, Honorable Eugene H. Nickerson, District Judge, presiding, and the issues having been duly tried and a decision on the motion of Ives Laboratories, Inc. for an injunction against defendants' alleged unlawful acts of trademark infringement, unfair competition, and violation of §43(a) of the Lanham Act having been rendered in an opinion dated April 15, 1980.

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that:

(a) defendant Sherry Pharmaceutical Co., Inc., its officers, agents and employees and persons acting with or for them, be and hereby are permanently enjoined from directly or indirectly using as a trademark or trade name or as a component thereof the word CYCLOSPASMOL or any name, mark or word confusingly similar thereto or colorably imitative thereof, including but not limited to SPASMOL in connection with the sale of drug products, including the drug of the generic name of "cyclandelate" and from printing, publishing, distributing, displaying, offering for sale or advertising or in any other way using for the purposes of selling or advertising cyclandelate the word SPASMOL or any colorable imitation thereof, whether alone or together with other terms or designs; and

(b) all other counts of the complaint herein be and the same are hereby dismissed.

Dated: Brooklyn, New York
April 28, 1980

s/ Eugene H. Nickerson
U.S.D.J.

EXCERPTS FROM REPORTER'S TRANSCRIPT OF TRIAL PROCEEDINGS DATED JANUARY 21-30, 1980

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

Civil Action No. 78 C 372 (EHN)

IVES LABORATORIES, INC.,

Plaintiff,

v.

DARBY DRUG CO., INC., et al.,

Defendants.

Pursuant to Supreme Court Rule 30.5, the page of the official transcript where the testimony is found appears in brackets. For the convenience of the Court, the name of the witness testifying appears at the initial instance where such testimony is set forth. It should also be noted that the official transcript is numbered as follows:

Trial Testimony on:

Jan. 21, 1980 — pp. 1a-126a;

Jan. 22, 1980 — pp. 1B-115B;

Jan. 23-30, 1980 — pp. 1-995.

* * *

Excerpts of Trial Proceedings

[Lowenkron, Tr. 18a] Q. What is Ives' business? A. They research, manufacture, and bring to the market and sale of pharmaceutical specialties.

Q. What do you mean by, "pharmaceutical specialities"? A. Chemical substances which have therapeutic effects that are used in the treatment of diseases.

Q. Approximately how many major drugs is Ives now distributing? A. About five.

Q Is cyclospasmol one of them? A. Yes, it is.

Q. What is the therapeutic indications for Cyclospasmol? A. It is a peripheral cerebral vasodilator.

Q. For us laymen, what does that mean? A. It opens the blood vessels to permit it more flow of blood.

Q. How many dosage strengths is Cyclospasmol sold in? [Tr. 19a] A. Three.

Q. What are they? A. One hundred milligram, two hundred milligram, and four hundred milligram.

Q. How long has Ives been selling the two hundred milligram capsule? A. Since '62.

Q. What color is that? A. Blue.

Q. Has it always been blue? A. Yes.

Q. How long has Ives been selling the four hundred milligram capsule? A. Since 1975.

Q. What color is that capsule? A. Blue and red.

Q. Has it always been blue and red? A. Yes.

Q. Do the Ives capsules have any imprint on them? A. Yes.

Q. What is the imprint on a blue, for example? A. The name, "Ives" in script and the NDC number.

[Tr. 20a] Q. On the four hundred milligram capsule? A. The same.

Q. Has that always been true, sir? A. Yes.

Q. Did you participate at all in the decision by Ives to select blue as the color of the capsule for the two hundred milligram? A. Yes, I was a member of the group that did the selection.

Q. Could you describe for the Court the circumstances which led to that selection? A. Well, we wanted to select a color that was distinctive and had some application to our company colors which were blue.

Q. You, however, — do you not at Ives sell capsules in colors other than blue? A. Yes.

Q. Why was that a factor in connection with the Cyclospasmol capsule? A. It was the first major product that we brought to the market and thus afforded us an opportunity to give it a distinctive color reminiscent of our company color.

Q. Did you participate in the decision to select blue and red? [Tr. 21a] A. Yes, I did.

Q. What were the reasons, if any, for selecting that particular color combination? A. Well, we wanted to retain the blue for continued identification as a Cyclospasmol product and another color red to distinguish it from the all blue two hundred milligram capsule.

Q. Now, Mr Lowenkron, I will show you what has been premarked Plaintiff's Exhibit 1 — after the defendants see what I am showing you.

(Exhibit shown to counsel.)

Q. (Continuing) I ask you to look at this exhibit and explain what the various elements in the exhibit are.

What is in the upper left hand corner? A. A white powder.

Q. Does it look to you like Cyclospasmol, cylandelate powder? A. Yes, it could be.

Q. What is the middle bin of the top of that exhibit? A. A clear, hard gelatin.

Q. Is cyclandelate ever sold in powder form? A. No.

[Tr. 22a] Q. Is the capsule one method for containing the powder so that it can be conveniently used by patients? A. Yes, it is.

Q. What is the capsule made of? A. Hard gelatin.

Q. Does that have any therapeutic value in connection with the drug? A. No, it does not.

Q. And would you explain what is in the upper right hand corner of the exhibit? A. One hundred milligram Cyclospasmol tablet.

Q. In other words, you chose tablet form for one of the dosages? A. Initially, yes.

Q. So a capsule is not absolutely necessary? A. No.

Q. And what are the bottom left and bottom middle bins; what do they contain? A. The bottom left contain blue capsules which are used in the manufacture of Cyclospasmol two hundred milligram capsules and the middle bin contains blue and red capsules which are used in the manufacture of Cyclospasmol four hundred milligram capsules.

Q. They're empty, right? [Tr. 23a] A. Yes.

Q. Do you manufacture your own capsules? A. No, we do not.

Q. Buy them from an outside organization? A. Yes.

* * *

[Tr. 24a] Q. I now hand you Plaintiff's Exhibit 3 and ask you if you can identify that for the Court. A. That is a gelatin capsule wheel.

Q. Who is it from? A. R.P. Scherer, one of the manufacturers of hard gelatin capsules.

Q. What is the purpose of that wheel? A. To aid in the selection of color combination for capsules.

Q. I also show you Plaintiff's Exhibit 4.

What is that? A. This is a similar device by Park Davis, another manufacturer of empty hard gelatin capsules and it serves the same purpose.

Q. Could you explain and display how it works?

THE COURT: You take a look and see what you want. It seems clear.

* * *

[Tr. 27a] Q. What is the basis of your knowledge about the pharmacy practice?

THE COURT: Do you need to go into that? Every now and then I buy a drug.

MS. DRISCOLL: Mr. Cobrin had indicated that he didn't think I had laid a sufficient foundation for the witness' knowledge.

THE COURT: Do you know anything about what pharmacists do?

THE WITNESS: I at one time worked in a pharmacy myself as a senior pharmacist and I have been in the industry thirty-four years and I have spent many hours in pharmacies observing pharmacists in the process of doing their work.

Q. How has cyclospasmol been promoted? A. Through — of course our sales force — through direct detailing efforts to physicians and pharmacies and by means of print promotion in trade journals to the pharmacists and in medical journals to physicians and by direct mail.

Q. And how many people does Ives have employed to do detailing of a product such as Cyclospasmol? A. Approximately 230.

THE COURT: I recollect from what was in the papers, the promotion is primarily to the doctors; is that right?

THE WITNESS: Yes.

THE COURT: The pharmacist doesn't make a judgment as to which brand unless there is some generic?

THE WITNESS: The only time we advertise to the pharmacist if we come out with a new dosage or new size.

Q. Do the detail men also visit pharmacies? A. Yes.

Q. For what purpose? A. To inform him about the activities and to check stock.

THE COURT: You have to do your selling job to the doctor?

THE WITNESS: Yes, primarily.

THE COURT: Really, entirely. Why else would you — a pharmacist can't overrule a doctor, can he?

THE WITNESS: No, he can't.

THE COURT: Why would you want — you'd want to tell him you have a new size?

[Tr. 29a] Why would you promote it — other than for —

THE WITNESS: And check stock, I said.

THE COURT: And check stock. All right.

Q. Do all pharmacies have to carry Cyclospasmol? A. Only if they get prescriptions.

Q. I now show you what has been marked Exhibit 11, and I will ask if you will identify the material in that collection. A. May I take a minute?

THE COURT: Yes.

I take it it is promotional material?

THE WITNESS: It is a collection and if I may look a second in sequence according to time - -

THE COURT: Yes.

All of that was put out by Ives?

THE WITNESS: Yes.

THE COURT: Okay.

THE WITNESS: Both for direct mail and distribution to physicians.

Q. Yes, — to whom was it distributed — I'm sorry — you anticipated my question.

Do you know approximately how many would be distributed for each of the promotional pieces? A. Depending upon how well the piece is received between 150 and 50,000.

[Tr. 30a] Q. I would like to refer to 11J.

Do you know how many times that particular piece was mailed out —

THE COURT: You mean, how many copies were mailed out or how many —

MS. DRISCOLL: I believe he said a mailing had approximately 50,000.

A. I recall this specific piece was one of the most successful ones I had and I think mailed about ten or twelve times.

Q. That is in color? A. Yes.

Q. Shows the color of the two hundred milligram capsule? A. Yes.

THE COURT: Somewhere between 500,000 to two million?

THE WITNESS: 500,000 and 600,000.

THE COURT: You said 50 to 150?

THE WITNESS: Yes, but this particular piece — counsel asked me about this particular piece and I said ten or twelve times. That would be 500,000 to 600,000.

Q. Would you now identify Exhibit 12, please? [Tr. 31a] A. These are two versions of what we refer to as the basic information brochure therapeutic committees which contains the entire scientific and clinical literature of Cyclospasmol and contains a brochure that addresses itself specifically to nurses who are charged with the care of elderly patients receiving cyclospasmol.

Q. To what category of persons would Exhibit 12 be distributed?

MR. COBRIN: On something like this we have an objection and if you would sustain it, it would save some time. It seems to me there is a stipulation, at least as to Premo, that we entered the market in January of '76. If this literature was disseminated subsequent to the date when we entered the market, I don't see how they can rely on it. She'd have to show priority.

THE COURT: I don't see why not.

MR. COBRIN: The question is, they have to show that they have some property right before we entered the market. They can't develop their property right subsequent to our entry into the market.

THE COURT: It may show strength. I think I will take it.

* * *

[Tr. 34a] MS. DRISCOLL: This is 11J which is one of the promotion pieces that went out. I believe that went out ten or eleven times. That shows the color of the two hundred milligram capsule.

(Exhibit shown to the Court.)

Q. Do you know approximately in what years 11J was distributed? A. I'd have to look on the back.

Q. Would it tell? A. The date is —

THE COURT: It doesn't say here. It says the patent number issued 8/67, this one.

THE WITNESS: It was during the year '67.

Q. Would you identify Exhibit 15, please? A. These are several versions of the Cyclospasmol physicians' file card which contains the prescription information on Cyclospasmol.

Q. Is that intended for daily use of the physicians or used during his practice? A. Well, many physicians maintain a book in which they keep these file cards for reference.

[Tr. 35a] THE COURT: May I see that, please?

(Exhibit shown to the Court.)

THE COURT: They keep this in a file with their other drug things so they can pick it out?

THE WITNESS: It's prescription information.

THE COURT: So they'll see what they should prescribe?

THE WITNESS: Yes.

THE COURT: What do you call that, physician's file cards?

THE WITNESS: Yes, your Honor.

Q. And I now show you Exhibit 16, sir.

What is that? A. These are detailed folders which each of them highlighting one feature of the product which was used by our representatives and detailing physicians on Cyclospasmol.

Q. I now will show you together Exhibits 7 and 8 and ask if you will identify them to the Court. A. These are the physicians' samples on Cyclospasmol two hundred milligram and four hundred milligram which are distributed by our representatives to physicians in the course of detailing the product.

Q. They leave samples? [Tr. 36a] A. And they're mailed occasionally.

Q. Are you still sampling the blue 200 hundred milligram? A. Yes.

Q. The same quantities that you used to? A. Since the four hundred milligram has been marketed, the two hundred milligram was reduced commensurately.

Q. Sir, do you know the amount of yearly sales of Cyclospasmol in the two hundred milligram size? A. At the present time — can I refer to — I took notes.

THE COURT: Surely. You don't have them in your head.

MR. MARROW: May we see what he's referring to?

THE COURT: When he's finished you may see it.

It will refresh your recollection?

THE WITNESS: Yes.

A. In '69, two million five million three hundred and fifty-two thousand.

The four hundred milligram was four million eight hundred and thirty-four thousand.

Q. Could you tell us, if you do have a total, [Tr. 37a] since Mr. Cobrin is especially interested in before and after 1976, what were the sales of the blue two hundred milligram cyclospasmol prior to '76? A. I have a total from 1962 to 1979. It was eighty-nine million, approximately, and for the last ten years it was seventy-two million. So you take the differential between the time.

Q. Is it million unit dollars? A. Dollars.

Q. Has the sales of the two hundred milligram gone down in the last few years? A. Yes, they have.

Q. Can you elaborate on that? A. Well, of course, with the release of the four hundred milligram there was a reduction of sales in the two hundred milligram. If we go from dollars to units, there was a considerable reduction because at the same time there have been several price increases.

Q. Do you have a figure for the total sales of four hundred milligram blue-red cyclospasmol? A. Yes. Since the release in 1975 the total figure is seventeen million.

Q. Do you also know —

THE COURT: That is through '79?

[Tr. 38a] THE WITNESS: Yes.

Q. Sir, do you know the approximate amount of money that Ives has spent in connection with the promotion of Cyclospasmol? A. I would say in the last ten years, from between ten to twelve million dollars.

Q. And have you made any change in the way you promote or any special promotion efforts since the beginning of '76? A. No.

Q. Just the same as usual? A. Yes.

Q. Do you ever promote your product directly to patients? A. No.

Q. Do you ever prepare material that can be distributed by physicians to patients? A. Yes, we refer to it as patient instruction material.

* * *

[Tr. 43a] Q. Is this product for acute or long term therapy? A. It is for chronic therapy.

Q. What does that mean? A. Long term therapy, it doesn't cure anything.

Q. You mean you keep taking it to alleviate a condition; is that what you're saying? A. To either alleviate or prevent further deterioration.

Q. Do you know what the — if a patient was, for example, taking two hundred milligram Cyclospasmol, do you know what the average number of capsules that he'd have to take per day would be? A. Four to eight.

Q. What about the four hundred milligram? A. Two to four.

Q. Can you describe if such a thing exists the category of patients who are more likely to be taking Cyclospasmol? A. They would be in the upper age groups.

* * *

[Tr. 45a] Q. Why is it not accurate? A. Because we haven't changed — we haven't changed the thrust of our advertising.

THE COURT: In other words, even before other folks came with vasodilators, you had the same kind of advertising — in other words, it wasn't a comparison type thing?

THE WITNESS: No, it wasn't.

THE COURT: Okay.

Q. Are there other vasodilators on the market? A. Yes, there are.

Q. What are some of them? A. Vasodilin, Arlidin, Pavabid, Cerespan, Roniacol, to name a few.

Q. Are they cyclandelate or another form? A. They're different chemical entities.

Q. Are you the leading vasodilator on the market? A. No.

* * *

[Tr. 52a] A. One of your tablets is blue, but in coloring tablets, you have a different situation. I am not a technical man, but in order to color an uncolored tablet you have a problem, especially if you have four different ones.

Q. Why are all the dosage forms of Isordil different colors, why didn't you keep several dosage forms — A. To distinguish them from each other. They're the same size.

Q. Is that the same reason that the four hundred milligram capsule of Cyclospasmol is a different color from the two hundred milligram capsule? A. As I testified before, we retained the blue and then we changed one segment of the capsule.

* * *

[Tr. 62a] Q. Many patients are given starter samples of Cyclospasmol by physicians? A. Yes.

Q. And they are provided by Ives, right? A. Yes.

Q. After the starter sample is given, the patient fills the prescription or refills the precription [sic] at a pharmacy, right? A. He has it refilled, yes.

* * *

Q. In the case of Cyclospasmol the patient [Tr. 63a] becomes familiar with the color because the treatment and management of peripheral vasodilator disorders require continuous treatment, right? A. Yes.

Q. This extended exposure leaves the patient with a strong visual picture of the appearance of the product he is taking, right? A. Yes, I believe you're quoting from my —

Q. Affidavit? A. Affidavit.

Q. And the patient relies on the appearance of the product to assure himself that he's receiving a proper medication? A. Yes.

* * *

Q. During your direct testimony you referred to Exhibits 17A, B and C as documents given to a physician to be given to his patient giving the medication? [Tr. 64a] A. You'd have to show it to me. Yes.

Q. Can you show me where on this literature, Plaintiff's Exhibit 17A, B and C reference is made to the color of the medication? A. There is no reference made to any medication. It is not only custom, but a physician would not use any of these materials if there was a reference to any drug.

Q. The patient is never given any literature which contains a reference to the color of the drug; is that correct? A. No that is correct.

Q. The two hundred milligram capsule of Ives, that is the name Ives imprinted on it? A. Yes.

Q. Isn't it on the capsule so that somebody will see the Ives name and identify it as an Ives capsule? A. It depends on the circumstances under which an individual looks at the capsule.

THE COURT: What do you put it on for?

THE WITNESS: It is together with the NDC number to identify the capsule in case a prescription is question.

* * *

[Tr. 67a] Q. There is no literature that goes to the public which makes a reference to your drugs by color; is that correct? A. We are not allowed to distribute literature to the consuming public.

Q. Would you answer my question, am I correct or incorrect? A. You're correct, obviously.

Q. Okay.

Now, you say you detail your Cyclospasmol product; is that correct? A. Yes, it is.

Q. And that is an expense to Ives, is it not? A. Yes, it is.

Q. And that expense to Ives is included in the cost of the drug when you sell it to your customers; is that not correct? A. Yes, it is.

Q. And generic drug companies don't detail their products, do they? A. No, they don't.

* * *

[Tr. 69a] Q. You said to your counsel that you were injured by — I guess you were referring to the defendants selling their cyclandelate product? A. Yes.

Q. You found out about it in 1976; is that not a fact? A. Yes.

Q. When did you feel you were injured, at what point in time? A. Well, this wasn't — it was a gradual process. We do review new and repeated prescriptions.

Q. Were you injured in '76 when you knew the defendants were out with their product? A. Yes, and the year after.

Q. And you waited until '78 to bring the suit? A. It was gradual.

Q. I understand.

[Tr. 70a] Q. When did you feel that you were injured so severely that you had to bring the suit? A. Obviously prior to instituting the suit.

Q. So for the first two years you were not injured sufficiently enough; is that correct? A. It was a gradual process.

* * *

[Tr. 79a] Q. Now, you stated, I believe in connection with the questions of Mr. Marrow, that you believed your detail men would mention the generic word cyclandelate once in making a presentation to physicians at least once.

Would you explain why would that happen?

A. They're instructed at the end of the presentation when they leave the file card to make reference to the fact that the file card is for cyclandelate at least once, and the same thing is done in the literature.

Q. When are they given this instruction? A. Early during the training.

Q. You train detail men? A. Yes, we do.

Q. In training them, do you tell them what to say? A. Yes, we do.

Q. Also, in connection with Mr. Marrow's questioning and this may have been a misstatement or perhaps I heard it wrong.

I believe Mr. Marrow referred to the Cyclospasmol one hundred milligram capsule. In fact, is the one hundred milligram dosage form a capsule or is it some other form? A. It is a buff tablet.

* * *

[Bovoso, Tr. 85a] Q. Where do you work? A. New York is my home office, but I travel throughout the country.

Q. Can you tell us, for the record, what a medical sales representative does — is that the same as a detail man? A. Yes, it is. A sales representative basically calls upon doctors, hospitals, pharmacies and nursing homes detailing his product, making the doctor aware of them, leaving him samples and leaving him third-party material which will support the claims that are made by the company.

Q. And were you a medical sales representative in connection with the Cyclospasmol product? A. Yes, I was.

Q. And can you tell us approximately how many physicians you visited each week in connection with Cyclospasmol? A. In the normal week between 25 and 40 physicians.

Q. And how many pharmacies would you visit per week? A. Twelve to eighteen.

Q. Hospitals? A. Five to eight.

THE COURT: This is per —

[Tr. 86a] THE WITNESS: Per week.

Q. How — over what years, Mr. Bovoso, did you make these visits in connection with the Cyclospasmol product as a medical sales representative? A. 1967 through 1974.

Q. And can you tell us, for example, what your visits to physicians in connection with Cyclospasmol would have entailed? A. Yes. It would be the detailing of the doctor about that particular product, leaving him third-party substantiation, leaving him broad sides, which are put out by the company which would point out the bulletined points made in the third-party literature.

Q. What do you mean by third-party literature? A. Studies that have been done by physicians that are not affiliated with Ives Laboratories.

Q. I will show you, Mr. Bovoso, what has been marked Plaintiff's Exhibit 14 and ask you if that is the kind of material to which you're referring. A. Yes, it is.

Q. And was that material used in connection with detailing Cyclospasmol? A. Yes, it was.

Q. Now, do you, over the course of the year [Tr. 87a] revisit some of the physicians that you already visited? A. Yes.

Q. As a sales representative? A. Yes.

Q. Now, about how often would you revisit any individual physicians over the year? A. According to the material that you have and earlier in the game we're talking about, we visited the same physician between once every six and once every eight weeks. You should see the same physician roughly every six weeks.

Q. How long would your visit with the physician be in terms of time, each visit? A. With the actual physician it could vary from five minutes to half an hour, sitting in the office maybe another half-hour or so.

Q. Have you ever in your course of experience as a sales representative have any difficulty in getting appointments with physicians? A. Sure. Some physicians just see a salesman maybe once or twice a year. Some physicians probably not at all. There are few of them, but there are some.

Q. Now, I ask if you will look at Plaintiff's Exhibit 7 and 8, Mr. Bovoso, and tell me what, if anything, [Tr. 88a] a detail man would do with 7 and 8 —

* * *

THE COURT: Are you in charge of telling detail men what to do?

THE WITNESS: I was at one time, yes.

THE COURT: Answer it as of the time.

A. When you gave the doctor the product and told him as much as you could about the product and presented him with third-party material, you'd take out a sample and present him with it, making him aware of the product, how the dosages were to be prescribed as to the package insert, and leaving him all third-party material that we deemed appropriate at the time.

Q. Did you do this personally during your time as medical sales representative? A. I did it as a medical sales representative and district manager. I had the responsibility of training some of the people that came out of New York.

Q. Did you do that in connection with Cyclospasmol? A. Yes.

Q. What is the training school in New York to [Tr. 89a] which you refer? A. We have a training department in New York which trains our new representatives in some basic anatomy and physiology courses and some basic product knowledge.

Q. Do you yourself have any medical background? A. No.

Q. Do some sales representatives have some medical training? A. Yes, a number of them are science students when they were in high school — college — some may have been pre-med.

Q. How did you learn what should be said about Cyclospasmol when you were a sales representative? A. When I first came with Ives, the training is not as elaborate as it is today. I was taken by a district manager into a motel room for a week or ten days and he spent that time with myself and another individual, with a little book that they had which was used to train the man and the uses of our particular product and its competition.

Then you went into the field and were given a lot of things to read and put together. If you wanted to learn your trade you went home at night and did some reading.

Q. Do you know whether there are any other [Tr. 90a] vasodilators on the market today other than the defendants' or generic cyclandelate in blue or blue/red capsules? A. None, to my knowledge.

Q. Now, would you please explain to the Court what you as a medical sales representative would have done when you visit pharmacies as opposed to physicians; what is your role? A. You'd go into a pharmacy, tell him that you were working in a particular area, especially if you're new or the area is new to you and we were a relatively small company and had large materials at the time and you'd be new in the area. You go into the pharmacy and tell him that you had been calling on the doctors, you'd detail him similarly to the way you'd detail the doctor, make sure he had your product in stock, if not attempt to secure an order through the company or a wholesaler.

Q. Could you describe your visits as a medical sales representative to hospitals and particularly in connection with Cyclospasmol? A. Well, you did the same thing at a hospital as you did in the doctor's office. You called on physicians and then the pharmacy.

Also you would like to make sure that the pharmacy had your product in stock in view of the fact that [Tr. 91a] you were detailing the doctors who were on the outside who may have a hospital practice who would be putting the patients into the hospital.

* * *

[Tr. 107a] Q. What did you do when you got to Ohio?

* * *

THE WITNESS: I met with the salesmen and the district manager and asked him to fill me in as to what happened.

A. Then, what happened? A. We — I then went to a nursing home where he knew this drug was being distributed and I talked to the girls, told them that I was from New York, I was developing a unit dose package and since they found this was so nice would they mind giving me one.

A. Did they give you either or both Exhibits 26 and 27? A. They gave me quite a few.

[Tr. 108a] Q. Did they know you were removing it from the premises? A. I told them that I was talking it with me to develop something like that.

MS. DRISCOLL: I would like to call the Court's attention to 26, cyclandelate, Cyclosposmol.

THE COURT: Yes.

Q. Does the blister pack identified as Exhibit 26 contain Cyclospasmol? A. Well, we didn't think it did because there was no marking on it at all saying Ives.

Q. And Exhibit 27, which says Cyclospasmol, does that contain Cyclospasmol? A. No, for the same reason.

Q. It has no Ives name on it; is that correct? A. Correct.

Q. Did you pay for these samples? A. No.

Q. Did anyone ask you for payment? A. No.

* * *

[Tr. 120a] THE COURT: Going back to finding out about who had a propensity to substitute, if you find that your — the sales of your product are drying up or being reduced considerably, that indicates to you that one possibility is that he's substituting?

THE WITNESS: Yes.

THE COURT: That is all it indicates to you?

THE WITNESS: Yes.

THE COURT: Because there might be other possibilities that you mentioned?

THE WITNESS: Yes.

THE COURT: Then in order to find out whether, in fact, he's substituting or not, then you would go and shop them?

THE WITNESS: Only if this was initiated by the office. To do a shop on our own, I have never done that.

THE COURT: Is that a big deal to go send someone there and shop them?

THE WITNESS: You mean to make that decision on my own at the time?

THE COURT: No, I mean to physically, is that very difficult?

THE WITNESS: It is very easy to do.

[Tr. 121a] THE COURT; Once you have the information that may alert you to the possibility that he is substituting, it is easy for you to send someone there to make a shopping and then you know for sure?

THE WITNESS: Yes.

* * *

[Tr. 8B] Q. I believe I asked you when detail men are taught how to detail there is a discussion about who the competition is, is that correct? A. Yes.

Q. Who do you regard as the competition? A. Other vasodilators.

Q. Who would they be? A. Arlidin Isoxsuprine, Papaverinehydrochloride.

If you would like the trade names I will give them to you.

A. Who manufactures those products? [Tr. 9B] A. Papaverinehydrochloride is manufactured by a number of people, USV, Marion; Arlidin is manufactured by USV; Isoxsuprine by Mead Johnson.

Dihydroergotimines are manufactured by Sandoz.

Q. These products are detailed in competition with your detail men? A. Yes, they are.

Q. When you teach a detail man about learning who the competition is, generally you stress your vasodilator is better or can do better than the competitors? A. Or does things differently, safer or better.

Any number of aspects.

* * *

[Tr. 10B] Q. You previously testified that detail men checked the stock of Cyclospasmol in pharmacies. A. That is one of their functions.

Q. In the pharmacy doesn't some pharmacist keep their stock by source so that it would be in one place? A. Yes.

Q. Is that a common practice? A. No more common than the other practice.

Q. Are detail people assigned a particular territory? A. Generally, yes.

Q. And do they visit all the doctors which are in that particular territory? A. They visit pre-selected doctors.

Q. How are those doctors pre-selected? A. You only have a limited number of hours in a day and limited number of time to do any particular job.

[Tr. 11B] They have to take those particular doctors that they can establish a rapport with or in a specialty that uses those particular items.

If you are selling vasodilators you wouldn't see an Obgyn.

Q. They visit doctors regardless of whether they have purchased Cyclospasmol or not? A. Yes.

* * *

[Fine, Tr. 33B] Q. Have there been any occasions in your experience, sir, in which you have prescribed the same drug in the same dosage form to the same patient but in a different color? A. Yes, there have been occasions.

Q. Do you know for a fact specifically? A. Yes, I do.

Q. And can you tell the court some specific instances when this happened? A. Well, I know of a number of specific instances where for example I changed one patient's antidepressant medication from a drug called Sinequan to another drug called Adapin, which in fact is the same compound, Doxepin hydrochloride.

Q. You say this happened with one patient. Was it only one, sir? A. It happened with several patients.

In fact, it has happened with seven patients that I know specifically of over the past 12 months, approximately.

Q. How do you happen to know this specifically? A. I know it because I have looked at the medication sheets of patients that I have seen in the [Tr. 34B] clinic over the last year.

* * *

[Tr. 35B] Q. Dr. Fine, I ask you if on page 423 there is a photograph of the Sinequan capsule to which you just referred. A. Yes, it's right here.

Q. Shows the color, does it not? A. Yes.

Q. Now, I refer you to page 422 and ask if the Adapin capsule is shown in color on page 422. A. Adapin is right here.

* * *

Q. I ask Dr. Fine if you would show the court which entries you referred to so the court can see the color differences. [Tr. 36B] A. It is a variety of colors depending on dosage.

In fact, it is the 25 and 50 milligram which I believe I prescribed.

* * *

Q. Has this happened, in your experience, this change of color in connection with any other drugs that you know of? [Tr. 37B] A. Well, I know for a fact that I have prescribed Librium, which is a very common minor tranquilizer. There have been several occasions where patients have in fact come back with their medication for the next appointment and had different color capsules because the Librium had been dispensed as chlordiazepoxide, which has different colors.

Q. What color is Librium? A. Ten miligram is a black and green capsule.

Q. Is it your testimony that when the patient came back he had different color capsules? A. That's right.

Q. Did any of these patients exhibit to you any anxiety about the change in color? A. Not anxiety. They questioned why they were given a different pill or different capsule and were told obviously why it was.

Q. After you told them did they refuse to take it or express any anxiety? A. I have never experienced that.

Q. Did you ever notice any change in the therapeutic effect of the drug on such patients after the color change occurred? A. No, I didn't.

[Tr. 38B] Q. Is there a pharmacy in the hospital with which you are associated? A. Yes.

Q. Do you know the practice of that pharmacy insofar as the purchase of prescription drugs is concerned? A. Yes.

I believe they are on what they call a bid system where they buy the cheapest form of medication available and will in fact prescribe that medication even if it is written under a different proprietary name.

Q. Does your hospital pharmacy carry a lot of generics? A. Yes, it does.

Q. Do you know of any instances in which the pharmacy has dispensed generics in a color different from the name brand — branded product of the same kind of drug obviously? A. There are several examples of that.

Not necessarily only in generic. It might prescribe a cheaper form of the same drug, but a proprietary brand, whichever they find cheaper in the bidding process.

That has occurred within — when I have [Tr. 39B] written "Tofranil," Imipramine hydrochloride, which is the same drug but in a different shape and form. Same dosage.

Q. Is Tofranil in that instance the market leader? A. I don't know if it is the market leader. It is probably one of the first — was the first produced and it is the one that I have traditionally used over the years, the past ten, 12 years.

As the patent has become available to other companies, other companies have produced various forms.

Q. What is the therapeutic indication? A. It is a trycyclic antidepressant medication.

Q. Do you know of any difficulties in connection with your patients, for whom you prescribed Tofranil when another drug of a different color was prescribed in its place?

* * *

A. I know several patients have asked me after admission to the hospital, for example, because they were on the same medication that they were admitted with, but the actual form of the medication has appeared different [Tr. 40B] to them and several patients have asked me why am I getting different medication, and my answer is it is not different, it is the same and I have not noticed or been told of any ill effects from that.

Q. Do you know any examples in connection with your hospital pharmacy other than in Imipramine? A. Librium is the classic example because it is a widely prescribed medicine and this is prescribed by the hospital pharmacy both in-patient and out-patient in the cheapest generic form available to the patient which is different in color from Librium.

Q. Are there any other products? A. I believe Amitriptyline, is also marketed or prescribed by the pharmacy or dispensed under a different name but I am not absolutely sure of its specific color, but I think it is different from Elavil which is a commonly-prescribed form.

* * *

Q. Do you know the source of the Amitriptylene dispensed in your hospital pharmacy? A. I am not absolutely sure of it, no, I am not.

* * *

[Tr. 42B] Q. Are the symptoms of arteriosclerosis, disorientation, difficulty in learning, difficulty in remembering things that happened recently and so forth? A. Those are symptoms.

Q. Are there any others? A. Confusion.

Deterioration of personal habits, personal care. Sometimes mood changes. It is complex and different in patients.

Q. Is cyclandelate prescribed? A. It is one of the medicines that is available, yes.

[Tr. 43B] Q. Have you prescribed it for patients suffering that disease? A. Yes, I have.

Q. In some patients is Cyclospasmol contra-indicated if the arteries in the brain are so hardened that dilating blood vessels would drain blood away from the brain? A. That is still a controversial area.

Some argue it is the case and some others would argue there is no such thing as a steel syndrome.

My prescribings have been done in patients' relatively early stage.

I wouldn't be hesitant by prescribing it in patients more deteriorated but I would be doubtful of efficacy.

Q. Do you have any doubt of patients in early stages of cerebral arteriosclerosis? A. I think the evidence is controversial. I found it is better than placebo and therefore I have used it as adjunct to therapy, never in and of itself.

Q. Do patients suffering from the symptoms of arteriosclerosis sometimes take more than one drug — do they also have other diseases that they are suffering together with? [Tr. 44B] A. Yes.

Q. Is that fairly frequent? A. I would suggest that it is, yes.

* * *

[Tr. 47B] Q. So if he were taking 200 milligram capsules he would take twice as many? A. Yes, if that was the way it was prescribed.

Q. If he confused his ergot alkaloid schedule with his cyclandelate and took that many ergotalkaloids capsules or tablets or whatever a day, would that cause a physical problem for the patient? A. Obviously it would be very unsafe.

Q. Would that also be true if he was taking a diuretic on the wrong schedule, might become dehydrated? A. Of course.

Q. Have you in your experience ever observed a patient who carries more than one medication in a pill box or a single container? A. Yes, I have.

Q. Do you consider this a healthy practice? A. No. I think it is a very bad practice.

Q. You have advised against it? A. I have advised patients to separate off dosages of drugs whenever they can, so they don't get confused.

Q. Is it possible that a patient with cerebral arteriosclerosis might forget the instruction because of the symptoms of the disease? A. It is possible.

[Tr. 48B] Q. In communicating with a patient, Doctor, do you ever refer to the color of a drug capsule for example — would you say take this blue capsule three time a day, take this red at meals and take the yellow before you go to bed? A. I try never to do that.

Q. Are you successful? A. Most of the time, I think.

Q. Does the patient ever refer to the color of the capsule when speaking to you, in asking you how many times should I take the blue capsule or things like that? A. That happens.

Q. Frequently? A. Depends what you mean by frequently. It certainly happens. It is not the most frequent thing to occur.

It does happen.

* * *

[Tr. 50B] Q. Now, when you have in the instances that you describe on direct changed the brand of the drug that was being prescribed and thereby changed the appearance of the drug, in those instances that you prescribed, you said that the patients asked you questions about it, is that correct? A. That's correct.

Q. And they were unsure that they were getting the proper medication, is that correct? A. They were taking what the medication was that they were getting.

THE COURT: I think you said some of them [Tr. 51B] said why was my medication changed.

THE WITNESS: That has been said too.

THE COURT: Yes.

Q. So isn't it safe to say that patients particularly on maintenance drugs such as cyclandelate or Cyclospasmol become accustomed to the appearance of the capsules that they are taking on a daily basis? A. Patients do become accustomed to the tablets that they take daily, yes.

Q. In the patient's mind they sometimes rely upon this appearance to be sure that they are — to receive some assurance that they are taking the proper medication, is that correct? A. Sometimes they do.

* * *

[Tr. 53B] Q. You indicated that a number of patients carry a daily amount of medication in a pill box? A. Yes.

Q. Despite the fact that it might not be the best medical practice, many people do it to the contrary? A. They don't do it after seeing me if they retain their relationship with me. They divide their medicine but they continue to do it. When they see other doctors they do it.

When I see patients it is not infrequent when they will present a bottle with different types of medication.

Q. Despite your advice there are a significant number of patients who do mix medication, they comingle them, is that not correct? A. It would be against my advice for them to do so and I would check with them regularly.

Q. That is not my question.

Despite what you advised and your feelings about it, nevertheless there are a large number of patients or a certain number that comingle? [Tr. 54B] A. There might be a number that would continue to do it.

Q. These patients who comingle, they rely on the sight of the medication to self-medicate? A. Some do; some don't.

Q. You spoke about Sinequan and Adapin. You said it is for anti-depressant, I believe. A. Yes.

Q. How long is a person on those medications? A. My practice is to recommend that they stay on either of those anti-depressants or any medication like that for a minimum of six months and they are reviewed on a regular basis and most patients with just enough depression require that for the better part of 12 months.

Q. Ever take it for life? A. Some people have taken it for ten, plus years and presumably will continue.

* * *

[Tr. 56B] Q. Do you believe if you have a patient who is a highly-confused state and doesn't speak English, that if you try to explain to him a certain medical situation and there will be a problem in understanding and accepting it? A. If a patient is confused, yes.

* * *

Q. Are you aware of a placebo effect in patients when they take medication? [Tr. 57B] A. Yes.

Q. Could you explain what that is? A. It is usually beneficial but sometimes not. The effect a patient has from a guard which is guarded from no chemical action, a chalk substitute, for example.

THE COURT: A sugar pill?

THE WITNESS: Or a sugar pill.

Q. But the patient believes he is benefitting by it, is that correct? A. That's right.

Q. And if the patient is then given a different drug is it possible that the placebo effect will be introduced at that point? A. I'm sorry, could you rephrase that?

Q. When the patient relies on that drug and that gives him a placebo effect — A. Yes.

Q. — now, an instance where a different drug is given, is it possible that the placebo effect would be interfered with? A. It is possible.

THE COURT: It would depend upon what you told him.

THE WITNESS: That's right.

[Tr. 58B] THE COURT: You might say this is a bigger and better — you wouldn't use the word placebo — a bigger and better drug, even though it was a placebo?

THE WITNESS: Exactly.

Q. Do you prescribe generically? A. Sometimes I do and sometimes I don't which is not a good practice of mine.

I have adopted American prescribing practices.

When I was trained I was always trained to prescribe generically and I tend to do what my colleagues do.

THE COURT: Why?

THE WITNESS: It is a poor practice.

THE COURT: What would be a good practice?

THE WITNESS: I think basic good practice would be to use a generic as a prescribing practice.

It induces a conformity and in terms of academic medicine, medical students would be more familiar with the basic molecule rather than a proprietary brand which might mean anything.

The reason I don't do it, because drugs have been marketed by drug companies under proprietary brands that have been advertised and those are the drugs that have led in the field [Tr. 59B] and been prescribed.

Tofranil would be an example which I have almost always prescribed as Tofranil because that is the name that everyone uses for it.

If I had my choice I would use generics. When I teach medical students I almost always do.

* * *

Excerpts of Trial Proceedings

[McCandless, Tr. 85B] Q. Can you describe the steps taken to develop a new drug for marketing in the United States?

* * *

A. Our first step is the actual chemical synthesis of the drug.

From there it goes to the pharmacology lab and they do what they call a profile and this is a battery of about ten tests to see if the drug has any activity.

If it does then they do more sophisticated animal testing.

We also do metabolism studies —

* * *

A. The toxicity of course is most important. Before the drug is actually put into any humans, there [Tr. 86B] there is usually a three-month — acute toxicity they call it. They do other toxicity studies.

They do — they put the drug into — usually mice, rats and rabbits, sometimes guinea pigs to get this profile.

THE COURT: Is this done before — this was done before you first started marketing Cyclospasmol, is this what you are talking about?

THE WITNESS: Those are the steps required for marketing a compound in the United States.

With the Cyclospasmol that was developed in Europe and some of these steps might have been missing.

* * *

[Tr. 91B] Q. Is Cyclospasmol a Paragraph 14 drug? A. Yes.

Q. Would you describe for the court what a paragraph-14 drug is? A. This was -- paragraph 14, so-called, because the actual paragraph 14 of Judge Bryant's order which exempted certain classes of drugs from — exempted certain classes of drugs from being removed from the market while clinical testing was ongoing.

Q. And do you know, sir, if within the last year during 1979 the Food & Drug Adminsitration [sic] published a notice relating to specifially those paragraph drugs that are peripheral vaso-dilators? A. Yes, that was in May of '79.

Q. Did the notice include cyclandelate? A. Yes.

Q. Did it include all other peripheral vaso-dilators as well? A. Yes.

Q. Has Ives filed a request for hearing with the FDA in connection with that notice? A. Yes.

* * *

[Tr. 92B] Q. What is the subject of the notice? A. It is revoking the exemption clause that was given to us for continuing the clinical investigation while the product was being marketed.

One notice revoked this and the other notice stipulated a time frame to remove the product from the market or request a hearing.

Q. And in connection with that notice, has Ives submitted further information to the FDA concerning the effect of the drug? A. Yes. We did in July of '79.

Q. And is there a date set down for a hearing on this matter? A. Not to my knowledge.

* * *

[Tr. 102B] Q. Who are the other companies that have filed requests for a hearing on this issue? A. The National Association of Pharmaceutical Manufacturers filed in behalf of a few of their members, and also I learned this morning that Premo Laboratories has filed.

MS. DRISCOLL: Your Honor, we have a stipulation that among the members of the association for whom requests for hearing have been filed Inwood, the defendant, is one of them.

Q. Do you know, Mr. McClandess, whether the paragraph fourteen exemption was granted to Cyclospasmol because of a medical need for the drug? A. Yes, it was. It was granted to about at least twenty therapeutic classes of drugs. They felt there was a medical need to keep it on the market during this time while it was being tested.

* * *

[Pangburn, Tr. 9] Q. Where is Persse's Prescription Shop? A. It's in Savannah, Georgia.

Q. And approximately when did you purchase Exhibit 19 from this pharmacy? A. To the best of my recollection, it was in January of 1978.

Q. Were you instructed to do so by anyone? A. Yes, sir.

Q. Who was that? A. Mr. Baron. Let me clarify that. That came from my district manager, who was told was on the —

THE COURT: All right.

A. (Continues) Under the direction of Mr. Baron.

Q. Now, Mr. Pangburn, did you obtain Exhibit 19 pursuant to a prescription? A. Yes, sir.

Q. And what did you do with the bottle in Exhibit 19 when you received it? A. I sent the bottles to my district manager.

* * *

[Tr. 11] Q. Mr. Pangburn, have you ever seen Exhibit 19 before? A. Yes, sir.

Q. Could you identify it for the record? A. This is a prescription that I acquired from Dr. Kessler yesterday morning.

Q. And where is Dr. Kessler located? A. He's in Savannah, Georgia.

Q. Did you have a prescription filled? A. Yes, sir, I did.

MR. RAUBICHECK: I show counsel an object which has been marked as Exhibit 90.

Q. Mr. Pangburn, would you — well, have you ever seen Exhibit 90 before? A. Yes, sir. I got this from Hillard's Prescription Shop in Savannah, yesterday.

Q. Could you identify it for the record? A. It's Cydel, 200 milligrams and the capsules [Tr. 12] are orange. Much the same as in this other bottle.

* * *

[Lipstein, Tr. 23] Q. And would you please state for the Court briefly your educational background?

* * *

[Tr. 24] A. Ph.D, Columbia University, MA, Columbia University. BA, Brooklyn College.

Q. And what courses do you teach at NYU? A. Marketing research, advertising research, quantitative methods in marketing, the marketing of financial services, design of experiments.

* * *

Q. Can you — A. I have taught other courses as well previously. Sample survey methods, statistical inference, analysis of variance, and other related statistical courses.

Q. Can you also state briefly your employment history with special attention to any part of it that relates to either statistics or market surveys? A. Yes. Previous to being professor of marketing at New York University, I was director of research, Senior[Tr. 25] Vice President and member of the Board of SSE and B, Inc., an advertising agency of substantial size, world-wide, about 850 million dollars in billing. As director of research I was responsible for all surveys conducted for the agency or clients throughout the United States. I was also chairman of the sub-committee on research world-wide, responsible for instructing the offices around the world on the latest methods and statistics and survey procedures. This ranged from 1965 until I assumed the professorship in New York University.

Prior to that, I was associate research director, director of information services and the vice president at Benton and Bowles, also an advertising agency and had similar responsibilities, primarily for General Foods, in the design and execution of a wide range of surveys. Prior to that, I was technical director, vice president of Audits and Surveys, responsible for the design and execution of sample surveys. Prior to that, I was mathematical statistician with the Bureau of Labor Statistics, responsible for the design of national surveys that the Department of Labor executed, as well as a whole series of methodological issues that they were concerned with.

Q. Did you design and analyze a survey in connection with this lawsuit? [Tr. 26] A. Yes, I did.

Q. How did this come about that you did so? A. I was requested by counsel to examine the problem and recommend a research design.

Q. And I'll show you Plaintiff's Exhibit 62 and ask if you can identify that? A. Yes. This was a letter which I sent to Miss Driscoll, in terms of my view of the problem and how to approach it.

Q. And what was your understanding, sir, of the purpose of the survey to be done? A. The purpose of the survey was to determine the confusion that existed on the part of people who take Cyclospasmol and their ability to recognize or identify the generic product cyclandelate as Cyclospasmol. Or their confusion on the issue.

Q. And in your original proposal. did you initially intend to do the survey of patients only? A. Initially, yes.

Q. In fact, was the final survey done of patients only? A. No, it was not. It included doctors.

Q. Why was that? A. Because statistically, it was impossible [Tr. 27] to reach patients without first going through doctors.

Q. Why do you say that was statistically impossible. A. Well, there are at most 100,000 people in the United States who take Cyclospasmol. This represents a very small percentage of the total population. It would take an inordinately large sample to find even a handful of these people. It is essentially looking for a needle in a haystack. Statistically it is called a rare event or scarcity sampling. And it would be statistically impossible to execute.

Q. In other words, you are saying you couldn't go to, for example, shopping centers I know a lot of surveys are done in shopping centers, could you have done that kind of random survey in this case? A. You could not have located any meaningful number of people through shopping center interviews and if you had taken a general population sample on an area basis, the likelihood of finding users of Cyclospasmol are almost nil. You simply compute the probabilities of 100,000 over roughly 200,000,000 population, you are dealing with a fraction of a per cent.

* * *

[Tr. 32] Q. And what category of physicians did you decide to use? A. I did not identify them in advance as to category.

Q. How did you identify them? A. The physicians — well, the first step was to determine roughly how many physicians there were in the United States.

Q. How did you do that? A. Who might be prescribing Cyclospasmol.

Q. Did you, in fact, determine how many might be prescribing Cyclospasmol? A. Yes. From IMS. IMS is a — one of the largest marketing research firms in the world, concerned with auditing of scripts that doctors write. From the IMS particular set of tables, I determined that there were some 32,000 general practitioners, full-time activity. There were some 12,000 part-time general practitioners. There was a lesser number of internists. Now, the IMS data showed that approximately 23 per cent of the general practitioners prescribed Cyclospasmol. If I multiplied that 23 per cent by the 32,000 doctors, I get an estimate of the number of general practitioners who prescribe [Tr. 33] Cyclospasmol. In the case of the part-time physicians, in discussion with the IMS people, who are expert in this area, they suggested working with half of the part-timers which are roughly six or 7,000.

* * *

THE COURT: You are going to show that they can't tell one blue pill from another pill? And you're going to show that a certain percentage of them say that it is Cyclospasmol?

[Tr. 34] THE WITNESS: Yes, your honor.

THE COURT: When they looked at it?

THE WITNESS: Yes.

THE COURT: Because they had heard of Cyclospasmol before?

THE WITNESS: They recognize the blue —

THE COURT: They wouldn't know whether it was Cyclospasmol or not unless they heard of Cyclospasmol before that?

THE WITNESS: Exactly, your Honor.

THE COURT: What is the big deal? You can't tell the — you can't tell one pill from another because they both look alike. Isn't that — isn't the likelihood of confusion very high?

THE WITNESS: Well, that is — the study demonstrates that —

THE COURT: Do I need you to tell me that you can't tell one blue pill from another? It seems to me I would draw that inference myself. And if no one has heard of — if the only drug that they have heard of, let's say, a vasodilator or whatever, they've been taking, Cyclospasmol, I assume they'd say yes, that is Cyclospasmol?

THE WITNESS: That is essentially the findings.

[Tr. 35] THE COURT: What do I need him to testify to that for?

MS. DRISCOLL: Your Honor, I do want to put this survey in to create a record. Just to clarify what was involved in this survey, so that you know more what the significance was .

THE COURT: What is the significance of it? I don't see the — I don't understand the significance of it. Someone has been using Cyclospasmol. It is a blue pill and someone shows them a blue pill and says, what is that. They say surprise, Cyclospasmol.

MS. DRISCOLL: Your Honor, the defendants in this case are making the claim that if they put their names on their blue pills, there will be no confusion and that is part of this case, your Honor. May I show you what will later be marked? This is what was identified as Cyclospasmol. It says Premo on it.

THE COURT: So they don't look that closely. I assume that a lot of people don't look that closely. I really don't see what it has to do with your case, at any rate because you are not selling — they aren't going out and selling to the consumer. [Tr. 36] You have to persuade the doctor to prescribe Cyclospasmol.

* * *

[Tr. 38] THE COURT: You only talked to physicians who were prescribing Cyclospasmol?

THE WITNESS: Well, I did not know what these physicians actually prescribed. And I will explain the source of these doctors in a moment, but, presumably these doctors were primarily prescribers of Cyclospasmol.

THE COURT: So they weren't in any doubt when they wrote out the prescriptions of the difference between Cyclospasmol and some generic cyclandelate, were they?

THE WITNESS: I don't know, your Honor.

THE COURT: All right.

BY MS. DRISCOLL:

Q. Now, from what source did you get a list of actual physicians' names — of physicians who were believed to have prescribed Cyclospasmol? A. The Ives Laboratories provided me with a source of list of names. These names were requested by the Ives people from their detail men, requesting the names of physicians who they believed were [Tr. 39] prescribers of Cyclospasmol. This consisted of the name, address and their telephone number and zip code. There were approximately 12,000 such doctors. Now, these doctors were listed on a computer run that you have in front of you.

MS. DRISCOLL: Your Honor, this is Plaintiff's Exhibit 68. I won't burden the Court with it. It is the computer run of 12,000 names.

THE COURT: Yes.

Q. Now, I believe you stated that the list given you by Ives contained approximately 12,000 names, whereas you thought there could be as many as 15,000 prescribers. Does the difference in the total in your mind, affect the validity of the universe and of the projections you can make? A. No. First the — it might actually be as low as 13,800. So, we are dealing with the 12,000 names represent anywheres from 80 to 90 per cent of all doctors who presumably prescribe Cyclospasmol. In survey practice, that represents a very substantial portion of the universe to be surveyed and almost any finding that we determined for these 12,000 doctors, almost irrespective of what the residual group we did not include, might represent, would in no way materially affect the [Tr. 40] results.

Furthermore, the likelihood is that the roughly 1,800 to 2,000 doctors not on the list would probably have the same characteristic as those on the list.

Q. After this printout was presented to you, Dr. Lipstein, what did you do? A. I requested that the — this computer listing be arranged by zip code, from the lowest numbered zip code to the highest numbered zip code.

Q. Why? A. This provided me with an automatic geographic stratification of the doctors across the country.

Q. And how many geographical areas across the country did you think it appropriate to survey? A. I used 20 geographic areas across the country.

Q. Why did you select 20? A. For two reasons. One given that I wanted a sample of 100 observations, 100 doctors and 100 patients. I felt the work load of five doctors per interview, per interviewer, seemed reasonable, which would imply 20 locations. Also 20 locations is a reasonable number of locations for estimating a single national characteristic.

[Tr. 41] Q. Now, what is the basis for that conclusion? A. Prior activity and experience in the survey field.

Q. And how were the names of these specific doctors then chosen? A. Based upon the count of 12,000 doctors and the decision to take groups of five doctors, this determined the sampling interval, that is the rate at which I would select doctors through the list, and I then chose a random number from a table of random numbers between one and that sampling interval, and that determined — by counting from the top of the list of doctors to that random number — that determined the first group of doctors to be selected.

Thereafter, systematically going through the list, every nth group of doctors was then selected until the entire list was exhausted.

Q. And did anyone from Ives tell you which geographical areas to select? A. No, they did not.

Q. Or did anyone of them tell you which physicians to select? A. No, they did not.

Q. Now, once the geographical areas were selected, were there any substitutions made? [Tr. 42] A. Yes, there were substitutions made.

Q. And why? A. I discussed the area selection with the Harry Heller Research organization, who was willing to execute the study and with their Field Director. And they pointed out two things, one, that some of the areas selected did not have a sufficient number of doctors for the purpose of interviewing, and that would mean that the interviewer would not be able to complete the assignment.

And, secondly, that in some of these areas quality interviewers to conduct the interviews were not readily available to execute the study.

My experience had demonstrated that the interviewer quality is as equally important as the sampling area itself.

So with this in mind we permitted some substitutions. But these substitutions were always made within a geographical strata so they were essentially equivalent in terms of representation.

Q. Were these substitutions made before or after the survey interviews were actually begun? A. They were made before the survey was in fact begun.

* * *

[Tr. 49] A. Yes. This is the package which the interviewers carried with them with the various capsules in the jar.

MR. COBRIN: Is there a label on that?

THE WITNESS: There is no label on this Exhibit.

A. (continuing) The interviewer was then instructed to pour the capsules on the desk or the table between herself and the doctor.

And the question was asked:

Do you recognize any of these capsules?

Q. Now, there are a variety of capsules there.

Could you tell me why the particular capsules were selected for use in this bottle shown to the physician?

* * *

THE COURT: Well, just tell me which capsules they are.

THE WITNESS: Yes. There were three blue capsules, two blue without any markings at all, and one blue with the marking Premo on it.

There were three red-blue capsules, two without any markings at all and one with the name Premo on it.

THE COURT: There were none with IVES on it.

[Tr. 50] THE WITNESS: None with IVES.

Q. Why were there none with IVES, Dr. Lipstein? A. Because the physician might examine the capsules and see the name Ives and then associate Cyclospasmol with Ives.

Q. Was there an attempt to keep Ives out of it? A. That is right.

MR. COBRIN: Objection to the leading.

THE COURT: Overruled.

A. (Continuing) Yes, obviously if the name Ives were there we could expect that some physicians, perhaps a considerable number, might associate Ives with Cyclospasmol and therefore I couldn't measure what we were attempting to measure.

Q. And what are these other capsules?

Is there a maroon and white capsule? A. There is a maroon and white capsule which has the name Diazide on it. There were three of those.

Q. And what else? A. There was also a clear and brown capsule, one of which says Pavabid on it.

The other two, one has a small name here, Central, and the other one has nothing at all on it.

* * *

[Tr. 54] Q. Why was it decided to include a list of drugs in the final survey? A. It became clear, and this is a very normal process in survey design as you develop the survey instrument, that it was desirable to imbed the products we were concerned with in a relative framework. And I give you a kind of equivalent example, we have seen very often a familiar product imbeded in an unfamiliar background, and when asked to identify it you can't identify it — you really don't know what you are looking at — because this object is imbeded in an unfamiliar background. And if you take that object and imbed it in a familiar background then you immediately recognize it for what it is. So it seemed appropriate to provide some sort of background from which, if there was an awareness, it would sort of position it.

Q. Would you identify 64-A, please? A. #64-A is called card A, which is a list of ten drugs which were shown to physicians.

Now, there were ten different versions of it.

Cyclospasmol is number one in the first card. It becomes two in the second card. It becomes ten in the 10th card.

We rotated the position of cyclospasmol to eliminate [Tr. 55] any possibility of what we call positional bias, that is, if Cyclospasmol had appeared always first it could have affected a subsequent response.

Q. Where did you get that list of drugs, Dr. Lipstein? A. Well, Cyclospasmol, Pavabid and Diazide were the three tablets contained in the jar.

I needed seven more drugs. And I took a list of the top 200 drugs that were prescribed by doctors and I selected seven random numbers.

THE COURT: Was that by brand name?

THE WITNESS: They are all brand names.

A. (Continuing) And I selected seven random numbers. And these random numbers determined the seven brand names that would be included on the list.

That is important for two reasons, one is that I wanted to introduce at every level I could some probability mechanism, because that is the nature of survey processing.

And the other is by using random numbers it avoided any biases of an unknown nature, or any adverse factors that might have affected the results.

Q. Why didn't you put cyclandelate on this list? A. It is not on the list of 200, and did not come in.

* * *

[Tr. 59] MS. DRISCOLL: Your Honor, I would now like to show the witness Plaintiff's Exhibit 71.

Q. I would ask you if you know what 71 is?

MR. COBRIN: Are those the physician's forms? A. Yes. These are the physicians forms.

Q. I notice that the names, and addresses and telephone numbers of the physicians are whited out? A. Yes.

Q. Why was that done? A. One because — so that confidentiality was assured to the physicians.

Furthermore, it is a common practice, for example, the Census Bureau, the Bureau of Labor Statistics, and all Government Agencies assure all their respondents of the confidentiality of responses to statistical surveys.

That is standard Government practice that has existed for certainly 40, or 50 years if not longer.

It is also common practice, in marketing research to assure respondents that their identification will be held confidential, particularly with respect to something involving physicians and drug prescriptions, it seems to be all the more reasonable.

[Tr. 60] Q. Now, the physicians were also asked, were they not, on page three of the questionnaire if they can furnish the patients' names? A. Yes.

Q. Did they all do so? A. No, they did not.

Q. Were they given any criterion for selecting the patients whose names should be given? A. Only that they be able to respond, that is, that they be reasonably mentally alert.

Q. Now, does the fact that physicians in fact made to some extent the selection of the people to participate in the patient interview in your opinion bias the results of the patient interview? A. I do not believe so because the physician would have no particular reason first of all to select one patient verses another nor would he necessarily know what our objectives were. So I cannot see how any bias would enter into it through the physician's point of view.

Q. Were any payments made to the physicians that participated? A. Yes. They were paid a normal fee for an office visit.

And in addition a payment for names provided of [Tr. 61] patients who have been prescribed as cyclospasmol.

Q. Why was that second payment made? A. To encourage them to provide us with names.

Q. Was the payment for the work they would have to do? A. Presumably.

Q. Is it unusual to make a payment to a respondent in a survey interview? A. It has become more and more common practice to pay a respondent either with some small token gift or payment.

Even yesterday I received a questionnaire in the mail from a magazine, and attached to it was a dollar.

In effect I am not obligated to answer, but they were in effect paying in advance to encourage me to answer the questionnaire.

* * *

[Tr. 63] Q. Did you in fact in any instance hear the conversation between the doctor and the patient? A. No, I did not.

Q. Do you have any reason to believe that a patient would give incorrect information in response to question one?

* * *

A. I don't believe so and in inspecting the questionnaires, I do not recall a single questionnaire in which the patient reported that the doctor or nurse had told him about the intentions or content of the survey.

Q. I'll now show you Exhibits 88-A through C and 89-A through C, which are six prescription bottles. Would you identify the 88 group? A. The 88 group are three different containers, with different closures, containing blue capsules without any — one of them contains blue capsules without any markings. The second one also contains blue capsules, but this one sort of lifts off, again without any markings [Tr. 64] and the third one again contains blue capsules. Notice the closure of this one is different, and this one has the name Premo on it.

Q. And do those bottles also have labels? A. Yes, they do.

Q. Do the labels say cyclandelate? A. Yes.

Q. Does the one in your hand now also say Premo? A. Yes, it does.

Q. Would you identify 89 and do it very briefly since it's parallel? A. 89 is exactly the same except that it contains the red and blue capsule. One of them has the name Premo on it.

Q. Do all of the labels say cyclandelate? A. Yes, they do.

Q. Do they all also have a name on it, such as Inwood, or MD, or — A. Inwood, Premo and Rugby.

Q. Why were those particular capsules selected for this as opposed to using an Ives capsule? The same reason as in the physician — A. Exactly the same reason.

Q. Why were three bottles shown? [Tr. 65] A. Well, one, it was to distract to some degree. In other words, the emphasis initially was on sort of opening the individual jars. And there was one with identification on it as opposed to the others which were not. So that if you had — you had in effect writing on one capsule and not on the others.

Q. Now, after the initial questions were asked, were the patients, if they could not identify the drug, were they also shown a list? A. Yes, they were.

Q. Would you identify 65-A? A. 65-A is called Card B and has a list of ten drugs on it, again the first one on this one is Cyclospasmol, 9 other drugs, and the position of Cyclospasmol is rotated so that Cyclospasmol would not have what we call a position bias. Again, I made the selection of the remaining nine drugs. I used again the random number approach and the seven drugs that were selected for the doctor card were included in this and I selected two additional random numbers, to extend the list to ten for the patients.

THE COURT: Were those all — are they all brand names?

THE WITNESS: They were all brand names.

* * *

[Tr. 73] Q. Now, this study and the interview reflects an absolute number of people who made the identification you are referring to. Now, is it your belief that these absolute numbers can be projected to the entire universe of Cyclospasmol prescribers and users? A. Yes. The study design was constructed to provide for projection to the entire universe of doctors who prescribe and patients who take Cyclospasmol, through the random start and the systematic selection of the doctors throughout the list and the follow through with the individual doctors. So that one can quite comfortably say that these numbers are projectable to the entire population of physicians who prescribe Cyclospasmol and for patients who take Cyclospasmol.

Q. Now, in making this projection, to the entire universe is there a margin for error? A. Every survey is subject to a margin of error.

* * *

[Tr. 83] Q. I now show you Plaintiff's Exhibit 83 and ask if you will identify that? A. This is the report which I prepared, summarizing the findings of this shopping activity.

Q. Can you simply, the Court does have a copy of the — can you just point out the more significant findings? A. Yes. If you'll turn, let's see, 2, 3, 4, 5, pages, to the first table, which lists the Ives list of pharmacies and at the base, the second table down, it says, Prescription labeling when cyclandelate dispensed by pharmacists, we find that there were total in this particular list of 18 pharmacists who dispensed cyclandelate but in fact, cyclandelate dispensed and labeled as Cyclospasmol by 6 or 33 percent.

We turn to the next page. The table again at the lower part of the page prescription labeling when cyclandelate dispensed by pharmacists, and again there [Tr. 84] were 17 pharmacists who dispensed cyclandelate, and of those 17, cyclandelate dispensed and labeled as Cyclospasmol by four or again by 33 percent. Since — this is from the Hayes directory. And since the results of both the Hayes directory and the Ives list were literally almost identical, statistically the same, I felt free to combine the two into a total combined sample of pharmacists and when one looks at the next page, —

THE COURT: What were they asked? What was the prescription they were asked to fill?

THE WITNESS: The prescription, if I may show you, was for Cyclospasmol.

MS. DRISCOLL: The substitution permissible, your Honor.

THE COURT: Were substitutions permissible?

MS. DRISCOLL: Yes.

* * *

A. (Continuing) Now, because the results of both the Ives sample and the Hayes directory sample were almost identical, statistically, I was able to combine the two and in the third table, we have the combination of the two samples, which is now projectable for the State [Tr. 85] as a whole, in which we have a total of 35 pharmacists who dispense cyclandelate. Of those 35 pharmacists, ten, or approximately 29 percent had on the label cyclandelate and when they — rather they dispensed cyclandelate and labeled it as Cyclospasmol.

THE COURT: Did you have any — did you have any prescriptions that said — didn't say substitution permitted. Dispensed as written; is that what it says?

THE WITNESS: I don't — I believe they were all the same.

THE COURT: All said substitution permitted?

THE WITNESS: They all were the same, I believe.

THE COURT: All right.

THE WITNESS: Substitution permissible.

MS. DRISCOLL: Yes, your Honor. If I may speak to that? This was not for the purpose of showing illegal substitution, but for another purpose.

THE COURT: Okay.

Q. Now, may I please just note for the record that the boxes of exhibit — of those exhibits are 82 and I have marked as 82-A the copy of the prescription that [Tr. 86] Dr. Lipstein took from one of the envelopes.

THE COURT: There is no survey been made or shopping done to show what percentage of pharmacists make an illegal substitution that you are going to introduce?

MS. DRISCOLL: No, sir.

* * *

THE COURT: All right. Did any of the bottles say generic equivalent or have any letters or anything to indicate that it was generic? Did you make that analysis?

THE WITNESS: Yes. There was some — there were some labels which said Cyclospoasmol and then in brackets, generic.

THE COURT: What percentage were those that [Tr. 87] had in it generic?

THE WITNESS: I'd have to go back and read —

THE COURT: You didn't make that calculation?

THE WITNESS: No.

* * *

[Tr. 94] Q. Could you point out to me — which exhibit number is it, so the record will be clear? A. 67.

Q. Could you point out to me where in the — in the instruction sheet it advises the interviewer to tell the patient that his name will be kept confidential? A. I am not sure I could find that.

Q. Isn't that because it is not there? A. I'll take your word for it.

Q. You don't have to take my word. You can look at it.

* * *

Q. I simply assume there is no instruction to the interviewer that the patient was told that he — that his name was to be kept confidential? I'm sorry. The doctor. [Tr. 95] A. Again, I do not recall that there is a specific statement in it. If you say there is not, I would take your word for it.

Q. Okay. What was your understanding of why the survey was commissioned? A. The purpose of the survey was to determine confusion that existed among doctors and patients in identifying a blue and a blue red capsule.

Q. Was it for secondary meanding? A. I am not sure that I understand what secondary meaning is.

Q. Do you feel ill at ease using the term secondary meaning? A. Yes.

Q. Its not a term that you have heard, I take it? A. I have heard it used on occasion, but I still am not certain that I could interpret it properly.

Q. What do you think your cousel hoped the survey would find and prove?

MS. DRISCOLL: Objection, your Honor.

THE COURT: I will let him answer that.

A. Well, in a way — to my mind, it — I didn't care what they hoped the survey would prove. I was [Tr. 96] simply executing a research instrument. I presume they were hoping to observe reasonable levels of misidentification. But that was irrelevant to me.

Q. I take it that you wanted the survey to be as objective as possible in the implementation? A. I tried my level best.

Q. And the reason you wanted it to be objective was that we all recognize, I take it, that if there are any bias built into the survey, it can affect the result, is that not correct? A. That is true.

* * *

[Tr. 128] Q. Isn't it a fact that every interviewer was expected to review the questionnaire before he went out and conducted his interview? A. Yes.

Q. As a result of that, every single interviewer knew that Cyclospasmol was the subject of the survey? A. In a way, yes.

Q. Is it yes or no? You said in a way. Can you answer directly? A. Well, they knew that Cyclospasmol was the drug we were looking for for patients. Precisely what we were looking for. I don't think they could have determined.

Q. All I asked you, every interviewer knew that the survey was about Cyclospasmol? A. Yes.

Q. Didn't the card that was shown to the physicians substantially raise the incidence of identification? A. It increased it.

Q. Substantially? A. I will have to look at the tables to answer you.

No.

* * *

[Tr. 131] Q. If it wasn't representative you couldn't extrapolate? A. If it was not representative, it could not be generalized.

Q. Do you have Premo's Exhibit 26, September 24, 1979's proposal?

MS. DRISCOLL: I think that is Plaintiff's Exhibit, not Premo's.

THE COURT: It is 62.

MR. COBRIN: That is the number we used.

THE COURT: We'll go by the Plaintiff's since it is already in evidence.

MR. COBRIN: Okay.

Q. Can you turn to page four at the back which says, "research proposals continued"? A. Yes.

Q. In paragraph five it says, "patient will be shown sample of the Ives brand and its generic counterpart and asked to identify which is his brand of drugs." A. Yes.

[Tr. 132] Q. This proposal, I take it, was sent to counsel; was it not? A. Yes.

Q. And that test in number five was never utilized, was it? A. That's right.

Q. Now, in number three, it says, "interviewer, built to identify brand names of drugs.

Do you see why I am referring? A. Yes.

Q. This proposal was sent to counsel, wasn't it? A. Yes.

Q. And was it built to identify brand names of drugs included in the patient questionnaire or the physician's questionnaire? A. This proposal was a very early —

THE COURT: Just answer the question. Was it or wasn't it?

THE WITNESS: No, it wasn't.

Q. In number six —in number seven, the individual is asked to compare his own product with both the Ives and generic product and asked if he's able to tell which product he's currently using. A. Yes.

* * *

[Heller, Tr. 206] Q. How large is your staff at your headquarters in Port Washington? A. Our staff in Port Washington is approximately 25 people of which 15 are permanent people and another ten are brought in for specific projects.

Q. Do you have your own staff to do the field work in a study such as the study involved in this case? A. No, we do not.

The traditional way of doing field work in marketing and public opinion research is for the research company to contract with independent contractors throughout the country.

There are only one or two companies that have the luxury of their own field staff, and even in those the field staff is not nationally representative.

Q. Do you have an ongoing relationship with certain field supervisors you have used in the past? A. Yes, we do. We have used them as a company for [Tr. 207] seven years. And individuals in my company have worked with these field staffs for as much as 25 years in some cases with the same person.

Q. Has there ever been an occasion when you have been dissatisfied and had to terminate your relationship with a field supervisor? A. That has happened from time to time, yes.

Q. Now, in how many geographical areas did you have a field supervisor doing the interviews in connection with this particular study? A. 20 geographical areas.

Q. And where did the geographical areas come from?

Was there a list initially given to you? A. There was a computer run of physicians that was supplied to us. And the actual choice of the geographical area was done by a random number that was given to us by Dr. Ben Lipstein. And using the random number, and a specific skip pattern, we selected 20 geographical areas.

We then took those areas to see whether interviewers were available in those areas.

In cases where interviewing services were not made in that area we made a substitution to a chosen zip code area.

[Tr. 209] Q. And I asked if you can identify them? A. Yes. Plaintiff's Exhibit 66 is the administrative instructions which is a set of instructions that we prepare instructing our independent field supervisors on how we want the study conducted.

And Plaintiff's Exhibit 67 is the interviewing instructions which are written by us to instruct the interviewer as to how to go about conducting the interview.

Q. And did your firm have the final say as to what was to go into those instructions? A. Our firm submitted the instructions, as we usually do to our client, to make sure that anything in the instructions were not particularly out of order. But the specific wording and the way it was phrased was determined by our firm.

Q. And has any member of your organization ever received any award for drafting field instructions? A. Yes. My Director of Operations and Vice President, Miss Doris Lesansky —

MR. MARROW: I object to that, your Honor.

THE COURT: I will listen to it.

She drew good instructions.

MR. MARROW: What is it suppose to prove?

MS. DRISCOLL: Your Honor, I am not going into [Tr. 210] for frivolous reasons. But we do want to establish that every precaution was taken to select someone who would execute this survey properly. I am not doing this frivolously.

A. (continuing) And my V.P. Director of Operations, Doris Lesansky, was given the Silver Cup Award with respect to the Market Research Association, which is a national public interviewing organization, for excellence in field instructions, and she won that top award after two years of being the honorable mention. To get this award she has to demonstrate top facility in preparing instructions.

Q. Did she participate in the execution of this particular study? A. Yes, she did.

Q. Now, after the interviews had been sent to the field, what was the next step performed by Harry Heller Research? A. After the interviews were sent to the field we were in daily contact with the field to make sure as to how the study was being conducted.

The interviews were sent back to us and we submitted the interviews to an approach called validation, in which a sample of interviews from each interviewer is given to an independent company, and the company makes long [Tr. 211] distance telephone calls to make sure that the interview was conducted properly.

We asked certain questions to make sure that the interview was properly conducted.

THE COURT: Of whom did you ask those questions?

THE WITNESS: Of the respondent in the state.

THE COURT: You called the patient and you called the doctor?

THE WITNESS: Yes, this is correct.

Q. And would you identify for the record Plaintiff's Exhibit 76 please? A. Yes, sir. This is a letter from the company that does our validations. It is called Centrac Incorporated in New Jersey, demonstrating that they were given 141 listings and they had called at least a number of respondents for each interviewer. And they found no problems in the execution of the study by the interviewers.

THE COURT: What is the company that does the validation?

THE WITNESS: Centrac?

THE COURT: Oh, yes, Centrac.

So you had to give them the doctors' names and the patients' names and telephone numbers?

THE WITNESS: We give them a sheet of paper [Tr. 212] with the name, the telephone number and a list of validation questions.

THE COURT: And that is to assure yourself that in fact the questions that were on this questionnaire were properly asked?

THE WITNESS: Were properly asked, that is correct.

THE COURT: That didn't suggest anything to them, that type of thing?

THE WITNESS: That is correct.

THE COURT: How many did they call?

THE WITNESS: We asked them to validate at least 20 percent of each interviewer's work which meant on the average of one person per interviewer.

In the event there was any problem they were authorized to make additional calls.

THE COURT: Did you run into any problems on any of those?

THE WITNESS: No.

THE COURT: Not one single problem?

THE WITNESS: No, your Honor.

Q. Is that reflected in your report in front of you? A. Yes.

[Tr. 213] Q. Is it the ordinary practice in survey work to have validation work done by a company other than your own? A. This is done all the time by us.

Q. Now, did you participate, Dr. Heller, in the decision not to disclose in this case the names of the physicians and patients who had responded to the interviews? A. Yes, I did.

Q. And can you tell me what considerations you took into account in participating in that decision? A. The confidentiality of what we call respondents in survey research is almost a "given" in the marketing research profession.

Our organization is a member of the Council of American Survey Research Organizations, CASRO.

And in the business practices guidelines, this procedure is part of the CASRO policy.

In addition the United States Government in the Census Bureau has also established the fact that names of people interviewed as part of surveys done for the Census shall not be divulged to anyone.

The only exception to this is just for the purpose of validation.

[Tr. 214] Indeed very often we tell the Respondent that the only reason we are taking their name is just for validation.

The assumption in the industry has always been that in dissemination of the names of the respondents in a survey could be used to either further contact them or might institute undue harrassment of the respondent. And that would cause us serious problems in gaining public cooperation in surveys.

THE COURT: Is it because it might affect future surveys that you do not want the doctors and patients interviewed in the future.

THE WITNESS: Not necessarily future surveys. It is to effect — it's because the cooperation for the future was obtained with the promise that their name wouldn't be used.

THE COURT: Let us assume you went in and didn't promise confidentiality, would that create a problem?

THE WITNESS: I think what it would do is it would reduce the cooperation rate to a lower level than it was.

THE COURT: You would still get some cooperation but not as much.

[Tr. 215] THE WITNESS: Yes, that is correct.

THE COURT: That would be the effect of it?

THE WITNESS: Yes.

THE COURT: All right.

BY MS. DRISCOLL:

Q. Dr. Heller, I show you what has been marked as Plaintiff's Exhibit 86 and ask you if you will simply identify it for the record? A. Yes, that is the CASRO code of standards for survey research.

Q. What what is CASRO again, sir? A. It is the Council of American Survey Research Organizations. It is a group of 50 of the top public opinion research companies, along with our firm, such companies as Yankelovich I think it is, but that is close enough, and Gallup, and Market Facts, and Nielsen, all belong to it.

It is the group that establishes basic business practices and standards for a specific industry.

Q. Dr. Heller, are you aware that there were a fair number of physicians who either could not be contacted or who indicated no interest in participating? A. Yes, I am aware of that.

* * *

[Tr. 217] Q. Is there any way for you to determine from the questionnaires that were used whether a third person was present when the field interviews were taking place? A. No, there is no way of determining that.

I would say that having a third person available at the interview would be a tremendous departure from practice that interviewers are trained in all the time for the interview as between them and the respondent.

Q. Now, was the report sent back to your organization, the completed interviews, at some point? A. Yes. They sent back completed interviews.

Q. What would your staff do at that point? A. Well, the next thing we do is we went through a process called editing and coding in which the responses to the questionnaire are looked at, and an attempt is made to classify them and assign numbers to them so that they could be put on IBM cards or other data processing things can be done to them.

So they went through our coding and editing process, and after completion of that phase of the study we then had the cards keypunched and verified with the keypunching, and ran computer tabs which simply counted the number of responses in each category of the questionnaire.

[Tr. 218] Q. Do you know whether in tabulating the results your staff rejected any of the material that was sent out from the field? A. I know of several cases in which — as a matter of fact they came to my office on it — in which there were questionnaires that were rejected because the interviewer had failed to ask one of the questions in the questionnaire.

And we felt that rather than counting the interview anyway, since that question was there, we wouldn't count it at all.

Q. Would you be the person who would make the decision as to rejection or not in circumstances like that? A. In this particular case where there was a judgment I was the one that it reached.

But there may be other reasons for rejecting an interview that is made at a lower level than me, depending upon the way it is asked.

Q. Now, do you recall that in both the physician and patient questionnaire at some point if there had been no spontaneous response, the patient or physician was shown a list? A. Yes.

[Tr. 219] Q. Now, was the interviewer supposed to indicate on the form in which order the name Cyclospasmol was on the list given to the particular person? A. Yes. There was a line providing for the interviewer to write in a number between one and 10, according to the position on the list, whether Cyclospasmol was there.

Q. Was there ever an indication when the interviewer did not fulfill that requirement and indicate where it was on the list? A. Yes. We found, I believe, in the case of two of the physicians and in the case of three of the patients the interviewer failed to put the number there in the order.

Q. Were these questionnaires counted? A. They were counted in both cases rather than — yes sir, they were counted. In both cases the order was not critical to the result because in neither case was the patient — in two of the three cases the patient didn't even identify Cyclospasmol so therefore the order in which it was could not have biased the response.

Q. If they had not been counted presumably the results would have been more favorable to Ives position.

Is that right? [Tr. 220] A. Yes, that is right.

* * *

[Tr.222] Q. What is a typical sample size for a national survey? [Tr. 223] A. Well, that would depend upon the subject matter.

If it were to reflect a presidential election it might be between 1,200 and 1,500.

But I have done national surveys among architects on their specifications of door locks in which it was judged that 85 to 150 interviews were an adequate number of interviews.

Q. Have you ever done a national survey where your population size was about 200,000? A. Never.

You said 200,000?

Q. Right. A. That is right. Never.

Q. Have you ever done a survey where you had an 80 percent rejection rate, or refusal to speak to you? A. Yes. It is ordinary among physicians.

In doing the National Eye Care Study among opthomologists [sic] for Corning Glassworks, the refusal rate on Opthomologists [sic] was about 75 percent.

And the talk in the industry generally, experience in the industry among physicians, is that in getting physicians, non cooperating physicians, namely, where the survey is the first time we are asking them to cooperate, refusal [Tr. 224] rates as high as 80 percent are traditional.

* * *

[Tr. 226] Q. Do you remember during your deposition, you discussed toastem pop ups? A. Yes.

Q. You said when the product became generic, the people would call the generic product Toastem pop ups? A. Yes.

Q. Isn't it true with a drug that you would have the same situation? Speaking used to taking the branded [Tr. 227] product, when they started to take the generic, they would call it — even though it wasn't the same product, the same as with toast em pop ups? A. The toast em pop ups was in a different context then this.

What I had said about that, is that — is that — very often people come to refer to the product itself in terms of the best known product in the area.

Q. They use it to describe the product? A. That's right.

* * *

[Tr. 232] Q. The people who conducted the interviews were the respondents knew it was for litigation: Your answer: Yes, as a matter of fact, they were instructed if I am not mistaken to complete the questionnaire and do other procedures that are traditionally done." When you gave that testimony last Thursday, you thought that was accurate? A. Yes. I believe these instructions are Exhibits 66 and 67.

Q. When I asked that question you understand that I was speaking to the people speaking to the respondents, didn't you? A. Our communication to the interviewers is Exhibit 67.

Q. That is not the question. A. That is the only communication that we have.

Q. All I am asking you when you said that the interviewers who dealt with the respondent knew that it was for litigation. When I asked you about that, you understand the question you had no problem with it? A. That is correct.

* * *

[Bernstein, Tr. 234] Q. What does a field director do? A. A field director is in contact with the field, letters them for jobs, supervise as the job is in progress, calls the field to get bids on different jobs, checks over the interviews when they come back, basically that is my function.

Q. Did you perform those functions in connection with the interviews — survey that was done in this case? A. Yes, I did.

Q. With whom was your contact in the field? A. With the supervisors.

Q. Did you speak to interviewers? A. No.

Q. Just supervisors? A. Yes. I'm sorry, there were a number of times when I called for a report and the interviewer was in the supervisor's office.

She then got on the phone and gave me her report herself.

Q. Did you ever disclose to an interviewer that the survey was done for litigation? A. No.

* * *

[Tr. 239] THE WITNESS: If the capsules were not all the same, then we would certainly be told about it. If the name on the bottle would be — would say something and the pills didn't say something, then we were told about it.

THE COURT: Which bottles are we talking about?

MS. DRISCOLL: These are the bottles in Syracuse and Dayton —

THE COURT: These are the ones purchased?

MS. DRISCOLL: Yes. There was testimony yesterday about them —

THE COURT: I understand now.

Q. I show you what has been marked Plaintiff's Exhibit 109 and I ask you if you can identify that? A. Yes, I can.

Q. What is it? A. That is a letter to all the supervisors on the study telling them that somebody might contact them to ask them questions about our survey. Telling them that we accept full responsibility for the survey and that [Tr. 240] they should provide, since they have control over their interviewers.

MS. DRISCOLL: This is in connection with the problem raised this morning.

Q. Did you ever tell a field supervisor not to cooperate with an attorney or research organization that might call them about that? A. No, I wouldn't say anything like that.

Q. Was that your sole communication, Exhibit 109, with the field on this matter? A. Yes.

MS. DRISCOLL: I have no further questions.

Your Honor, I think in your question you inquired whether the bottles were purchased. That wasn't a purchase. You will recall the testimony said that Mr. Bovoso and Miss Brady went up and exhanged —

THE COURT: Excuse me, yes.

MS. DRISCOLL: It was that as opposed to some of the others that were substitution problems.

* * *

[Milnamow, Tr. 244] Q. Are you employed? A. Yes.

Q. Is it Mrs.? A. Yes, it is.

Q. By whom? A. By Harry Heller Research.

Q. What is your position? A. Coding director.

THE COURT: Pardon?

THE WITNESS: Coding director.

Q. Can you describe for the Court what a — the duties of a coding director are? A. Well, my function is basically as the Court has been over with Janet —

THE COURT: You're referring to Mrs. Bernstein?

THE WITNESS: Yes. She receives the interviews in her Department. After she receives the interviews and checks them in, they are given to my department.

Now, we check basically the count of the questionnaires that come in and then we process them, we put them in number order, and then we do an editing job. We edit the questionnaire [Tr. 245] to see whether the skip pattern has been followed, whether they followed the instructions and then after that we will then, if that seems to be all right and everything is fine; then we build a set of codes according to the answers that are given.

This is all to prepare the questionnaires for the keypunch for the data house.

Q. And are you aware that the brand name of the drug that was listed on some of the questionnaires is Cyclospasmol? A. Yes, I know.

Q. Are you also aware that in some of the returned questionnaires there were words somewhat like Cyclospasmol, Cyclospastic was one of them? A. Yes.

Q. And Cyclospasmol was the other? A. Yes.

Q. Who would make the decision whether words such as that were treated as a correct or incorrect answer? A. That would be my decision.

Q. Did you make the decision with respect to Cyclospasmatic that it would be counted as a correct answer? [Tr. 246] A. Yes.

Q. Were there similar words like that that you did not count? A. There were a couple of instances where there were words such as cyclo something or other or cyclo where it wasn't sufficient what the person was going to say.

Q. They were not counted? A. They were not counted as correct answers.

Q. Were there any other questionnaires that were rejected completely and did you play any role in deciding what was to be rejected completely? A. There were I think about four questionnaires that came in that the proper skip pattern was not followed.

Now, that was not my decision because in some cases we'll use that material.

However, I have a project director that I report to.

Now, that was discussed and it was decided that there was not enough information, since they did not recognize cyclospasmol according to the capsule that was shown and then they did — we didn't know whether they saw the cards physically or didn't. Since we count [Tr. 247] material whether they did see the cards, they were not used.

Q. Do you know of instances in which a completed questionnaire came in that you did not review? A. No, I do not.

Q. And did you either record or decide to reject every single one of the questionnaires? A. Yes.

* * *

[Lavalle, Tr. 261] Q. Mrs. Lavalle, are you employed? A. Yes.

Q. By whom? A. Myself.

Q. And what is the name of your company? A. Lavalle Research.

Q. What does Lavalle Research do? [Tr. 262] A. Market research firm and field interviewing.

* * *

[Tr. 263] How did this come about? A. We were contacted by the Heller Research to do a study concerning doctor and patients.

Q. Had you done work for Heller Research in the past? A. Many times.

Q. Were you told by Heller Research that the survey was to be used in connection with litigation? A. No.

Q. After being contacted, what did you then do? A. I contacted an interviewer.

Q. Did you anticipate when you heard that the survey was — what the survey was to involve that you might have problems? A. Yes.

Q. Why did you think you would have problems? A. It is generally very difficult to get to see any professional, most of all a doctor.

Q. What is the basis for your saying that? A. Several other studies throughout the years dealing with doctors.

Q. You have had to interview doctors in the past and had difficulty reaching them? [Tr. 264] A. Yes.

Q. In your years in the research field, have you noticed whether or not the willingness of people to cooperate in surveys has generally declined or remained the same or gone up? A. Declined.

Q. You have more trouble now then you did in the past in getting cooperation? A. Very much.

Q. And in your experience, is it unusual to offer a participant in a survey a gift or some monetary compensation? A. No, it is quite usual.

Q. And is it usual or unusual to indicate that you are making that offer before you actually ask the interview questions? A. Once the eligibility has been determined, it is usually before the interview has begun.

Q. What do you mean by determining the eligibility? A. So that it wouldn't sway the respondent in any way to become eligible for the study. Once those questions have been gotten through then to set up a little better rapport between you and he, you do tell him that there will be a gift at the end of the interview.

* * *

[Caraccio, Tr. 293] Q. Are you employed, Mrs. Caraccio? A. Yes.

Q. By whom? A. Lavalle Research Company.

Q. How long have you been employed by Lavalle? A. Since August.

Q. What is your position? A. I am an interviewer, I edit, I do office work, whatever.

Q. Did you participate in as an interviewer in connection with the survey we're discussing today? A. Yes, I did.

Q. At the time you participated, did you know the identity of the client that had commissioned the survey? A. Harry Heller, I did.

Q. Did you who his client was? A. No.

Q. Do you know today? A. No.

* * *

[Lawlar, Tr. 307] Q. Do you hold any positions in any professional societies? A. I am currently the president of the Pharmaceutical Society of the State of New York.

Q. In your pharmaceutical practice, Mr. Lawlar, do you purchase drug products containing the same [Tr. 308] active ingredients in the same dosage strength from more than one source? A. Yes, sir.

Q. Is this a common practice in your pharmacy? A. Yes.

Q. Are such drug products from different sources made in different colors? A. Yes, surely.

Q. How often? A. Frequently.

Q. For what reasons do you carry the same drug from more than one source? A. The pricing is one. One company is offering it at a lesser price than another, balancing inventory.

Q. Any other reasons? A. Not really. Convenience.

THE COURT: Well, I take it some physicians prescribe by brand name, don't they?

THE WITNESS: Yes, sir. They do.

THE COURT: So you have to have the different brands if they have different colors?

THE WITNESS: That's correct.

Q. Do you maintain patient profiles of your [Tr. 309] customers at your pharmacy? A. Yes, we do.

Q. Because of a change in prescriptions and by that I mean at one time you filled a prescription for a particular patient for a particular drug and the next month that patient came back with a prescription for the same drug but as Judge Nickerson mentioned, a drug made by a different company under a different brand name, have you ever dispensed because of such a change in prescription to the same customer, the same dosage, the same drug and strength that was different from the drug that the patient had previously been taking but the new medication was of a different color than that previous medication? A. Yes, I have.

Q. Has that —

MR. MARROW: May I have the question read back.

THE COURT: Yes. I think there was a misword in there, what you mean is, I think, it's the same drug generically?

MR. RAUBICHECK: Yes.

THE COURT: One time they had it in one color and then you fill it for them in another [Tr. 310] color.

Is that what you meant to say?

THE WITNESS: That is what I understood, yes.

* * *

Q. Has this occurred throughout your career as a pharmacist? A. Yes.

Q. Would you give examples of drugs which you have dispensed which have been made in different colors to the court, if you can? A. Ampicillins, there are eight or ten different companies I am familiar with that all make different colors of ampicillins, tetracyclines are all in different colors, certain anti inflammatory drugs, the hormones, different companies making the same sort of, same generic drug in different colors.

Many, many different ones, with the advent of the generic substitutions law, tremendous different colors.

Q. Have you ever received any inquiry from any of your customers concerning a drug that you dispensed, [Tr. 311] the same drug of a different color in a subsequent prescription?

Have any of your customers ever questioned you about the change in color? A. They had and we tried to head that over by telling them it's a different color but the same medicine.

Q. You communicated that to your customer? A. Yes, we do, we have a little sticker that we put on the bottle to remind us that it's a different color but the same medication, same drug.

Q. Has it ever happened that the patient, despite your efforts came back to you and explained to you about the change in color? A. I guess so.

Q. What do you tell the customers? A. We explained the color was changed because it's a different brand, or a different strength, and sometimes it's a different drug and they say, okay, fine.

Q. In any such instance because of the change in color, after you explained the situation to the customer, has the customer refused to accept the new medication? A. Never.

* * *

[Tr. 315] Q. You filed an affidavit in this case, did you not? A. I did, yes.

Q. I want to read from paragraph 6:

"When I tell a customer the drug product [Tr. 316] I am dispensing is from another source which accounts for the difference in appearance.

It has been my experience that when some patients ask questions all but a few accept the medication despite the color difference."

I assume at the time you submitted the affidavit in the case, which was June 1978, that the affidavit was true and accurate, is that correct? A. I would assume so.

* * *

[Tr. 318] Q. Have you ever had a patient come in and refer to his drug by colors, such as my red water pill, or my blue heart pill or something to that effect? A. I have.

Q. Do you know what a maintenance drug is? A. Yes, sir.

Q. What is it? A. It is a drug that is prescribed for over a long period of time for a chronic condition.

* * *

Q. Would you agree with me that cyclandelate is a maintenance Drug? A. Yes, sir.

Q. Antibiotics, are they maintenance drugs? A. No, sir.

Q. In other words, a patient might get a prescription take it for a week or so, hope that it will get better and that is it for the medication? [Tr. 319] A. Generally speaking.

* * *

Q. Do any of the people who come into your pharmacy comingle their drugs, that is to say, they have a daily regimen of drugs in a single pill box, or something like that? Are you aware of such instances? A. A few.

* * *

Q. You said that you talked to the patients when there is a change of color and would reassure them — I understand your current testimony to be they all accept your reassurance, is that correct? A. That is correct.

Q. How do you handle a situation where you have a Russian immigrant who just came to this country and doesn't speak English, and has been on medication for a month or so, [Tr. 320] and the color has changed? A. I never had that happen, sir.

THE COURT: They do not have that many in Harrison.

Q. Have you ever had it with a person who doesn't speak English, say a person whose native language might be Spanish? A. I don't recall, no sir.

Q. When there is a change in color I take it that it takes extra time for you to explain to the patient that they are getting the same medication only in a different color? A. I think that is part of the process of the pharmacists explaining the drugs.

Q. Do you explain the medication to every patient that comes into your store? A. As often as I can, yes sir.

Q. And does it take extra time when there is a change of color and there is colloquy between you and the patient? A. It takes an extra second or so, surely. It takes a few seconds.

* * *

[Tr. 323] Q. I do not want you to guess. If you know, please tell us. A. I don't known the name. I do have a generic. I do not know the manufacturer of it.

Q. Do you have any companies where you do know? A. Lederle, Squibb, Parke Davis. Those three anyway.

Q. Parke Davis is not a generic drug company, is it, in the sense that they detail drugs, don't they? A. They have a detail man, yes.

Q. Parke Davis Tetracycline doesn't sell as Tetracycline? It has a brand name, doesn't it? A. It does.

Q. Dexamethasone, what is that Drug? A. It is an anti-inflamatory, cortisone.

Q. Is that an anti-inflamantory drug? A. Yes.

Q. Is that a cream? A. Yes, it does occur in a cream. But the dosage form that I guess I mentioned before is a tablet.

THE COURT: It is not a capsule?

THE WITNESS: It is not.

Q. Who is the brand leader of dexamethasone? [Tr. 324] A. A pure guess, Merck Sharp and Dohme.

Q. That is not a generic company, is it? A. No.

Q. What other Dexamethasones do you stock? A. Hexadrol.

Q. Just tell me the company? A. Organon.

Q. Organon sells it under its brand name, doesn't it? They don't sell it under the generic name? A. That is correct.

* * *

[Tr. 327] Q. Let me ask you another question. How long have you been a pharmacist? A. 24 years.

Q. For these 24 years has not the prevailing practice been for generic companies to have look alike drugs? A. Yes.

* * *

Q. In your pharmacy, does the price of a prescription drug that you charge to a customer vary in relationship to the cost of the drug to you? [Tr. 328] A. Yes it does.

Q. Is it a direct relationship? A. Yes.

Q. Does the New York State Pharmaceutical Society play any role in enforcing the rules or ethical precepts with respect to pharmacists if they do something that is unethical or illegal? A. No, sir.

Q. So there is no equivalent of the Grievance Committee of the Bar Association in this Pharmaceutical Association, is that correct? A. That is correct.

Q. How many pharmacists are there in New York State? A. 15,000?

Q. How long have you been the president of this association? A. Seven months.

Q. Have you been a member of the Association prior to your being president, I assume you have? A. Yes.

Q. For how long? A. Ten years or maybe more, perhaps 14 years.

Q. Do most of these 15,000 pharmacists belong to [Tr. 329] the Association? A. No, sir.

Q. How many do? A. 2500.

Q. If a pharmacists [sic] is charged with doing something unethical or illegal, where is that charge made against him? A. The State Board of Pharmacy.

Q. Do you know how many charges concerning illegal substitution of one drug for another were made in the past year against a pharmacists? A. I have no knowledge of that at all.

* * *

Q. Mr. Lawlor, in your pharmacy how do you stock your products? A. I don't understand the question.

Q. Do you stock them by brand name? Do you stock them by alphabetical order? A. Alphabetical order.

Q. Now, when you get a prescription for a drug product, what is your general procedure in filling it? A. Well, I ascertain that the patient's name is [Tr. 330] on the prescription and that is correct.

The patient's age.

I examine the prescription of what it says and get the patient's records out.

I type the prescription label.

Get the pharmaceutical out.

Package it.

Label it.

Deliver it back to the patient and discuss the medication as to the condition with the patient.

Q. Now, when you get the pharmaceutical out how do you ascertain whether that is the correct pharmaceutical for what is prescribed? A. Well, I go to the drawer where it is supposed to be and I get the bottle.

And I am a pharmacist and I know the name of the drug, the generic name of the drug, and the strength.

Q. Do you look at the label on the bottle? A. Yes.

Q. You check that with the description? A. Yes, that is correct.

Q. Now, I will show you a bottle marked Exhibit 9 for Inwood.

THE COURT: Defendant Inwood's Exhibit 9.

[Tr. 331] Q. (Continuing) And a bottle — this is a container, and the box has been marked Plaintiff's Exhibit 6, and it contains a bottle inside —

MR. TROST: We marked this as Defendant's Exhibit 9A since this bottle is not marked.

Q. (Continuing) Now, if the patient comes in with the prescription that says Cyclospasmol on it what would you then do? A. I would go to the location in the pharmacy that Cyclospasmol is located, get the bottle and fill the prescription.

Q. Would you check that the Cyclospasmol, in filling it where it is labeled with — Ives' product? A. Well, if I am looking for Cyclospasmol it has to be Ives' product.

Q. And would you innocently confuse this bottle, which is 9A, with this bottle, Exhibit 9, which is labeled Inwood cyclandelate? A. Would I confuse them? No.

THE COURT: Which is the cyclandelate? The Inwood, is it not?

MR. TROST: Inwood Exhibit 9, your Honor.

THE COURT: And the other is Ives, I take it.

MR. TROST: We will mark it Inwood 9A.

[Tr. 332] Q. Now, after you get the bottle from the shelf, what do you then do? A. Count the required number of capsules and place them in my prescription bottle with my label on it, and dispense it to the patient.

Q. All right. Could you open up 9A and just pull a couple of capsules out.

(Witness complies.)

Q. Now, seeing those capsules you also check as to if there is any logo on the capsule? A. Only incidentally. If I have the bottle with them I know it is from that bottle.

Q. What would that logo tell you looking at it? A. That these are Ives, and the product number on it, which is they are identical.

Q. Now, could you open up Exhibit 9?

(Witness complies.)

Q. What does Exhibit 9 say on it? A. It says Inwood 258.

Q. And would you as a pharmacist innocently confuse that product which is labeled Inwood with the other product labeled Ives in filling the prescription? A. Not if I only had this bottle.

Q. You would confuse it? [Tr. 333] A. I would not confuse it.

Q. Has anyone at the Inwood Laboratories ever suggested to you that you should illegally substitute this product for Ives' product? A. No.

Q. Do you know offhand from what generic companies you have products stocked?

We are talking about companies that do not detail? A. I have some products by Zenith. I have some products by Spencer Mead.

Q. Do you know offhand any of the names?

THE COURT: Names of the product?

MR. TROST: Yes, names of the products. A. Spencer Mead, I guess it is their tetracycline that I have. I have folic acid from them.

THE COURT: What is that?

THE WITNESS: Cortisone.

A. (Continuing) Zenith I have their chlordiaz — epoxide.

I have Zenith's Dithenhydramine.

* * *

[Tr. 352] THE COURT: With respect to that particular drug, do you know of any instances where a drug has been illegally, so to speak, substituted a generic for a brand name?

[Tr. 353] THE WITNESS: I know of none.

THE COURT: Would it be your judgment that that is a wide spread practice among pharmacies?

THE WITNESS: I don't believe it to be wide spread, no, sir.

THE COURT: Now, in those cases where you may have forgotten there aren't any — if there aren't, tell me — but if there are cases where initially you don't explain to the customers, "Look, this is a different color, but it's the same drug as you have been getting before, has there been any such instances?

THE WITNESS: Where we have neglected to tell them there has been a color change?

THE COURT: Yes.

THE WITNESS: Yes, sir.

THE COURT: Can you tell us in those instances, if you can, what percentage of those people come back and ask you about it or question it?

THE WITNESS: I would say if we haven't explained that there is a difference generally there is a question as to why the color is different?

THE COURT: They'll ask you —

THE WITNESS: Why the color is different or [Tr. 354] whatever appearance it has.

* * *

[Price, Tr. 356] Q. Mr. Price, where do you reside? A. Nassau County, Seaford, New York.

Q. What is your occupation? A. I am a registered pharmacist. I am Director of Pharmacy at Nassau County Medical Center.

Q. Are you licensed to practice pharmacy in the State of New York? A. Yes, I am.

Q. For how long —

THE COURT: How long have you been at Nassau County Medical Center?

THE WITNESS: I started there in 1966 and I became director in '69.

Q. Before your tenure at Nassau County Medical Center, Mr. Price, did you practice pharmacy in New York? [Tr. 357] A. Yes, I did.

* * *

[Tr. 358] You order specific drugs from the Bureau of [Tr. 359] Purchases — you place orders and say, "I want to buy x drugs"? A. Basically that is one of the things. We let them know what our needs are. They establish a vendor at a price, and then we draw off the contract.

Q. Now, when the bureau purchased — buys a particular drugs [sic] pursuant to this competitive bidding system, what are the criteria by which a bid is awarded on a — when a supply contract would be awarded to a vendor? A. Again, it is competitive bid and it is on a generic basis.

Q. When you say "competitive," do you mean the lowest bidder gets the contract? A. It may not necessarily be true that the lowest bidder gets the contract for a specific drug. I don't know what formula they use. There are times that they may allocate one vendor — we get a catalogue price. They make the decision. I don't know. I am not party to it.

THE COURT: The lowest responsible bidder?

THE WITNESS: That is true.

Q. Is the color of a particular drug a part of the specifications for drugs that are to be purchased by the Bureau of Purchases? A. Color is not.

[Tr. 360] Q. You mentioned that the drugs are on a generic basis.

Does that mean when you order a drug from the Bureau of Purchase you order it by the generic name? A. Yes, it is the generic name.

Q. What is the typical term of a supply contract for a particular drug — for how long would this company — A. You mean the contract period?

Q. Yeah. A. Generally about a year.

Q. During your tenure as Director of Pharmacy at the Medical Center in Nassau, have supply contracts for the same prescription drug been awarded to different vendors in different years? A. Yes.

Q. Has this practice ever resulted in a change of the color of the dosage form of a given drug dispensed by your pharmacy? A. Yes, it has.

Q. How often has it occurred? A. Could be on an annual basis.

Q. Frequently? A. Yes.

[Tr. 361] Q. What is the reason for such a change in color? A. Change in brand — change in the supplier.

Q. Would you be able to give the Court examples of drugs made in different colors by different manufacturers or vendors, if you will, that have been purchased by the Bureau of Purchase and dispensed by your pharmacy over the past several years? A. Ampicillin, we have purchased from Bristol Labs as Polycillin, as a red and gray capsule. We now purchase it from Bristol as a white and brown capsule in addition.

Penbritin which is Ayerst, red and black and Principen from Squibb which is I'd say, sort of a lavender.

Eftextracyclin from Leatherly [sic, Lederle] as a blue and yellow capsule, Sumycin from Squibb. That is a pink capsule.

We have purchased isosorbide from Stewart as sorbitrate, that's the two and a half milligrams on sublingual tablet, that is white. A five milligram sublingual is pink. The ten milligram oral is yellow.

We have purchased Ives' brand of Isordil, two and a half milligram is yellow, five milligram is pink, the ten milligram oral tablet was white.

We have purchased chlordizepoxide from —

[Tr. 362] THE COURT: Do we need all these, Mr. Raubicheck? I'll listen to them if we need them.

MR. RAUBICHECK: I believe, your Honor, Mr. Price has indicated a substantial knowledge of drugs —

THE COURT: Fine, if you want me to listen, I will listen.

MR. RAUBICHECK: He in this connection, I believe, has prepared a list of such drugs in different colors. We could have him identify it.

THE COURT: He could have gotten through them by now. Go ahead. A. Chlordiazepoxide Squibb Noctec is an orange-red and we have purchased the same product or generic product from American Cyanimide as a green capsule.

Purchased ampicillin fromMerck, Sharpe Dome as Elavil. Ten milligram blue, 25 milligram yellow, 50 milligram brown, 100 milligram lavender.

We also used Hoffman-LaRoche's 10, 25, 50 is an orange, 75 is yellow, 100 milligrams is brown.

There are more, but I don't know how many more you want.

MR. RAUBICHECK: Thank you, Mr. Price.

[Tr. 363] Q. From your experience at Nassau Medical Center, has the dispensing by your pharmacy of the same prescription drug in a different color at a different period of time caused any resistance, to your own knowledge, from in-patients at the hospital? A. No.

Q. Have doctors indicated any resistance for prescribing different colors? A. They don't prescribe by color.

Q. How do they prescribe? A. They prescribe basically by generic name.

Q. What about nurses, have nurses come to you and expressed a resistance to — administer to in-patients drugs of different colors? A. As long as the material is properly identified, the nurse will administer the drug regardless of color.

Q. When you practiced — practice pharmacy before you came to Nassau Medical Center, did you ever dispense to a customer the same drug in a different color from the drug that the patient had been taking previously? A. Yes.

Q. And did you ever receive any inquiry from such a patient about the change in color? A. No. Normally if I was going to change the [Tr. 364] brand of an item for whatever reason was necessary, I would inform the patient, so that they were aware that a change was taking place.

Q. And in any of these instances, did a customer refuse to accept the medication? A. None.

Q. Based upon your professional experience in the field of pharmacy, Mr. Price, do you have an opinion on the question of whether drugs which are marketed under their generic name should be made in the same color and appearance as the same drug which is marketed under a brand name? A. No, they don't necessarily have to be the same color.

Q. And what are your reasons for this opinion? A. Well, one is personal, more or less. The fact that it can stand as a quality control test.

Q. Could you explain that? A. It is very simple. There are sometimes when you're talking to a patient and they say to you, gee, you know, the last batch of red tablets you gave me weren't quite as good as the green batch. It kind of alerts you to the fact that you may have a problem on your hands. It is something that you just can't tell by looking at it. It is [Tr. 364A] something that has to be taken internally, you know, and you get the response.

* * *

[Kittelberger, Tr. 378] Q. Would you take a look for a moment at these documents that were in the envelope, in Exhibits 82, 000, and turning your attention to this first document that you have in your hand, could you identify that for the record? A. This is a photocopy of the prescription which I presented to the Frankel (ph) pharmacy.

Q. And — Go on. A. On it he had go of it I identified it after leaving the pharmacy with the prescription, with the date, the name of the pharmacy, the price that I paid for the prescription and my signature.

Q. And were you instructed to make those notations on the copy of the prescription by Mr. Adler? A. I was.

Q. And what is this second document containted [Tr. 379] in the Exhibit? A. The second document is a stapled receipt, a receipt with, two receipts, I should say, one is a registered receipt and the other is a written receipt from the same pharmacy showing what I paid and also identified.

In one case it's just my name and date because the address was on the other side, on the register tape is the name and address of the drug store.

Q. Were you instructed to make those notations by Mr. Adler? A. I was.

Q. Could you identify this object that was within the envelope? A. This appears to be the prescription that I left on that date, because it has my initials, the date and I taped it on to the container when I left.

Q. When you say prescription, prescription bottle that you received from the pharmacy? A. Yes.

Q. Did Mr. Adler instruct you to make those notations on that tape? A. Yes.

Q. Now, Mr. Kittelberger, after you made the [Tr. 380] purchase, did you then place the prescription bottle in that manilla envelope? A. Yes, sir.

Q. That you have in front of you? A. Yes, sir.

Q. And did you make any notations on this envelope? A. Well, before I put it in the envelope, I would have to write on it, because of the fact that once it's in there, you couldn't write on it.

So before I sealed everything, I would seal then, I would write my report and identify it.

Q. Is that your writing on the outside of that envelope? A. Yes.

Q. Is that your signature on the bottom? A. Yes.

Q. Now, I take it that after you completed the transactions and wrote out your report, you placed the bottle and the copy of the prescription and the receipt from the pharmacy in the envelope, is that correct? A. Yes, sir.

Q. Now, what did you do with the envelope and its contents after that? [Tr. 381] A. I sealed it, and usually, if — on this particular day, I had other shoppings to and I kept it in my locked car until I returned home and I am not sure if I went to Mr. Adler that evening. I believe it was a day or two later that I brought all the prescriptions to him.

Q. Now, with respect to this particular exhibit, 82, 000, did you ever, you personally, ever open that prescription bottle from the time you received it from the pharmacy to the time you delivered it to Mr. Adler? A. No, sir.

Q. To your knowledge, did anybody else ever open the bottle? A. No, sir.

Q. Is it your testimony that this package and its contents remained in your custody during that whole period of time until you delivered it to Mr. Adler? A. Yes, sir.

* * *

[Lehmann, Tr. 399] Q. Were you a pioneer, sir, in the use of such [Tr. 400] drugs in the treatment of psychiatry in North American? A. I think one could say that because I introduced the first major tranquilizer or anti-psychotic drug and I was the first one to bring the anti-depressant imipramine or the first major anti-depressant into North America from Europe.

Q. I also notice that you hold the position of Director of Research of the State of New York Office of Mental Health.

What does that entail on your part, please? A. It entails coming to New York or Albany or both places about once a week for a day or two, and helping the — assisting the Deputy Commissioner for research in the mental health department for the State of New York with administering the research operation of the state.

There are three research institutions, state supported, and the administration of these three institutes and research, in general, is rather complex.

And I assist the Deputy Commissioner and the Commissioner of Mental Health in the running of this.

Q. What is the Royal Society of Canada of which you are a Fellow? A. The Royal Society of Canada is parallel to the British Royal Society. It is a community of researchers [Tr. 401] where one can only enter upon invitation by your peers. So it is an honor to be invited or to become a member — to be nominated a member of such a society.

To my knowledge I am the first psychiatrist to be elected to the Society. They have all kinds of scientists, astronomers, mathematicians, physicians, but I don't think any psychiatrists.

Q. Now, in your personal experience in connection with the treatment of patients over the years, has there ever been an occasion, to your memory, where you prescribed to a patient the same drug of the same dosage form, but it was a different color because it came from a different manufacturer? A. Yes. I remember several instances and two or three drugs where that happened.

Q. What were the drugs, sir? A. One was diazepam where it happened most frequently. The brand name is Valium made by Hoffman-LaRoche and I often prescribed — usually prescribe now the name Vivol, which is the name of diazepam, but made by another Canadian firm and it is green while Valium is yellow.

It is also a brand name Vivol but I think they have a license from Hoffman-LaRoche who make Valium and like generic drugs it is cheaper than the Hoffman-LaRoche. It [Tr. 402] looks different, but it is the same substance.

Q. In addition to Valium, has there been any other drugs where you recall having changed the color? A. Yes, Stelazine which is a brand name for trifluoperazine Hcl. It's originally made by Smith, Kline and French. They're now — it is under the name of Solium in Canada. It is made by Honer and by a British firm under another name.

I have prescribed solely Valium instead of stelazine.

Another drug is amitriptyline which is Elavil. The brand name is Elavil by Merk Sharpe and Dome and I have prescribed it under the name of Deprex, which is made by a British firm, Beecham Product, and it looks different, but it is the same substance.

Q. Now, I will refer you to the brand names because I can't pronounce the generic names.

What kind of drug is Valium? A. It is a so-called minor tranquilizer or anti-anxiety drug.

Q. What is Stelazine? A. An anti-psychotic drug against major illnesses.

Q. What is Elavil? A. It is an anti-depressant.

[Tr. 403] Q. In connection with this change of color, has any patient refused to take the medication because the color was changed? A. No.

Q. Has any — did any of your patients have an anxiety reaction as a result of the color change? A. No.

Q. Did you observe in any instance that the drug with the changed color did not seem to be working as well on the patients? A. No.

Q. Now, do you know what kind of product is involved in this suit you're testifying in? A. Yes, cyclandelate or Cyclospasmol.

Q. What kind of product is that? A. It is a vasodilator.

Q. Do you have an opinion as to whether or not a patient on a vasodilator would be more likely to be anxious and upset over a change in color as opposed to the patients you spoke about who are on the anti-depressant and schizophrenic drugs?

* * *

A. I don't think so. I cannot acknowledge why [Tr. 404] there should be a difference.

Q. Do you ever treat elderly patients? A. Yes.

Q. Have you also treated younger patients? A. Oh, yes.

Q. Has it been your experience that the elderly patients seem to have more confidence in their physicians than younger people do? A. In general, yes. They're easier patients. They have more faith in authority as a rule than the younger patients particularly the very young adults who have a general distrust in authority and therefore keep shopping around and criticizing and trying to tell the doctor what to do and so on.

* * *

Q. Do you have an opinion, Dr. Lehmann, as to whether it is medically necessary for the same drug in the same dosage form to also be in the same color? A. Medically necessary, I don't think so.

* * *

[Tr. 414] Q. Would you describe what a placebo effect is? A. It's a psychological effect of a drug which is not — for which there is no pharmacological basis.

If somebody is given sugar in a gelatin capsule and told it's an active drug against headaches, and if he has a headache and he takes the sugar capsule and the headaches disappears, it's not a pharmacological but a placebo effect.

Q. Is it sometimes usefull to change the appearance of a drug that a patient is taking in order to induce a placebo effect?

For example, in a patient with a psychosymatic [sic] illness, if a drug is given such as aspirin, and if the patient thinks it's not working, is it sometimes useful to give the patient the same drug in a different color and [Tr. 415] in that way try to induce a placebo effect? A. It may work.

THE COURT: This is a real effect, the placebo effect?

THE WITNESS: A very powerful effect. It may be a more powerful effect then the pharmacological effect.

It's unpredictable even in the same person.

One day they may react to it, the next day they may not.

Q. Every so often patients that you have seen who have cerebral arteriosclerosis also suffer from other diseases in addition to that? A. Yes.

Q. Do some of these patients see a number of doctors, perhaps one for psychiatric problems and one for a physical problem? A. Yes.

Q. In some cases do the different doctors each prescribe the — a different drug for the patient, depending upon the specialty and the malady? A. Yes.

Q. Are some of these arteriosclerotic patient [Tr. 416] who are on different medications, self-medicating take the drugs at home by themselves? A. Yes.

* * *

[Getson, Tr. 432] Q. Based upon your professional experience and training, Doctor, will a responsible emergency room physician ever attempt to make a positive identification of an overdosed drug based upon color and appearance alone? A. No.

Q. Based upon your experience, will such an emergency room physician attempt to make a positive identification by reference to the product identification section of the Physician's Desk Reference? A. No.

Q. What reasons do you give for that last statement? A. The Physician's Desk Reference, if I can use the abbreviation PDR?

Q. Yes. A. Is a descriptive guideline publication that physicians use for that alone. In the emergency room situation [Tr. 433] we cannot rely on that because the colors of the medication as identified in the PDR are usually not accurate. In fact, I believe that is stated in the beginning of the PDR's identification section.

Another problem with using a color match up situation there are — there are several prescription drugs that look alike and are indeed at opposite ends of a chemical spectrum which would lead one to disastrous end if he tried to treat a patient specifically when you're dealing with another medication.

The third aspect of that, there are many over the counter drugs. In fact, some of them are frequently abused that are identical to the drugs that appear in the PDR.

Q. By what? A. By appearance, color, shape.

Q. In that regard, Doctor, I would like to show you a document, after showing it to counsel, which has been marked Plaintiff's Exhibit 114 for identification, and ask you if you have ever seen this document before? A. Yes, I have.

Q. Would you identify it for the record? A. It is — entitled, "Drug Abuse, a Manual for Law Enforcement Officers."

[Tr. 434] Q. Who published it? A. The Smith Klein French Labs in Philadelphia.

Q. I call your attention to the fold-out on page 46 of the document, and I ask you if you have seen that before? A. Yes.

Q. Could you identify it for the record? A. This is as they describe it, the non-prescription medication describing and showing — showing the prescribed drug next to the over the counter drug, and this is — they list amphetamines in one column and barbituates in another.

Q. What is the point of that fold-out? What point does the publication try to make? A. They show clearly that identification of medication purely by appearance is impossible.

Q. Dr. Getson, if an emergency room physician were to attempt to make a positive identification of an overdosed drug based solely on color and appearance, do you have an opinion based upon your professional training and experience as to whether or not this will be potentially harmful to an overdosed victim? A. Yes, this could be disastrously harmful.

* * *

[Tr. 439] Q. Did you file an affidavit in this case? A. Yes, sir, I believe I did.

Q. Have you reviewed it recently? A. Yes.

Q. You stand by what it says? [Tr. 440] A. Yes, I do.

Q. Would you refer to paragraph five, please. (Document shown to the witness.) A. Yes.

Q. I want to read to you the section on the dispensed prescription bottles not available.

"The physician will ask a family member or a friend or a relationship as to the overdosed drug could be found. They would give him an oral description of the appearance of the drug."

When you made that statement, what did you intend that they do with the information relating to the oral description of the drug? A. Very often people identify a drug not only by color or shape, but by identifying marks and numbers, and very often I have had people tell me that they take a white pill with a four on it, certain identifying characteristics.

* * *

[Tr. 441] Q. Could you turn to paragraph c.

"In those instances where the attending emergency physician knows the pharmacist who dispensed the overdosed drug he'll contact the pharmacist for correlation for the color and appearance of the drug with the pharmacist's patient profile records."

That is your statement? A. Correct.

Q. Isn't it a factor here where they use the color as some sort of aid? A. If the color and appearance of the drug is in some way able to help the pharmacist in describing — in prescribing — in identifying what kind of medication was dispensed in a chemical since that is helpful for the pharmacist. In a therapeutic sense it has no bearing on the treatment of the patient.

THE COURT: I don't understand that. Explain it to me. That will be helpful to the pharmacist in finding out which drug it was?

THE WITNESS: Well, your Honor, as you know [Tr. 442] there are many drugs that are prescribed and dispensed that are of various colors with a similar chemical composition.

Sometimes — I am speaking as a physician and not a pharmacist — sometimes in my experience a pharmacist can, with guidelines, look up his records and find out what a patient was prescribed.

THE COURT: And the color might be a part of the aid which would help him do that?

THE WITNESS: As described to me by a pharmacist, yes.

* * *

[Tr. 443] Q. Do you know what color Dilantin is? A. Yes, white capsule with a red strip.

Q. Librium? A. I believe it is various strengths in several colors.

* * *

[Sorenson, Tr. 507] Q. Just so that I know what you are saying no to; or what you are saying you gave some consideration to, how would you have gone about finding 100,000 estimated users of cyclospasmol in the entire country other than by using the means that Dr. Lipstein used?

What would you have done? A. Well, as I told you I have not made a thorough going definitive effort to determine how I would have done, since I had not been commissioned to do so.

I did, in responding to his Honor's question or perhaps remarks, did comment that there were other wasy [sic] that at least it occurred to me.—

One would have involved a screening process that indeed would have been time-consuming and costly.

[Tr. 508] Q. And who would you have screened? A. I would have screened individuals who could be contacted for instance by telephoen [sic] on a random probability basis thorughout [sic] the country.

Q. Any other ways occur to you? A. At the moment, no. But I would be happy to give it further thought.

Q. Now, how would you have gone about finding the appropriate universe if you were asked to find prescribers of cyclospasmol? A. This does not deal with my testimony, but I guess that does not matter.

THE COURT: No.

Answer the question.

I listen carefully to your testimony.—

THE WITNESS: All right.

There are one of two ways basically of securing the names of physicians who have prescribed cyclospasmol.

One is to go through the detail men that your survey organization did. The other would be to secure as exhausgive

[sic] a list of physicians as possible, perhaps confining them to certain categories of physicians, and then to screen those [Tr. 509] individuals by telephone or by letter or a combination of telephone and personal visit for their use of Cyclospasmol.

* * *

[Tr. 559] Q. What do you think is a good response in a situation like that?

* * *

THE WITNESS: The problem is that a good response rate is not necessarily the best you can get. At the same time we know that some response rates are unrealistic to anticipate. I have no answer. I know that response rates are difficult with physicians. There's no doubt about it.

* * *

[Tr. 560] Q. Dr. Sorensen, assuming for purposes of this question that there are approximately 100,000 persons in the United States for whom cyclospasmol has been prescribed at one point or another, do you have any opinion, based [Tr. 561] on your experience, as to how many households would have to have been telephoned in order to get a representative response? I believe telephoning was one of the ways you suggested we could reach patients. Q. Well, that — one could certainly develop a rough calculation. Assuming that there are approximately 68 million households — not knowing the correlation between telephone ownership and the prescription or the recipients, if you will, consultation of cyclospasmol, but assuming for this rough movement that there is approximately equal correspondence, it would mean obviously, dividing 65 million by 100,000, that would represent an obviously very, very large number.

Q. Would it have been extraordinarily expensive? Would it not? A. It would have been extraordinarily expensive.

Q. And time consuming? A. Correct.

Q. Now you indicated this morning that you had reviewed the questionnaires and that in four instances you noticed that the word "cyclospasmol" had been misspelled. A. Yes.

* * *

[Tr. 566] THE COURT:

* * *

They have been getting cyclospasmol and it has come in the blue tablet.

THE WITNESS: Yes.

THE COURT: And the pharmacist substitutes a different capsule, not tablet, capsule.

THE WITNESS: Yes.

THE COURT: And let's assume for the moment now that it's perfectly proper for him to do that because the physician has signed under substitutions permitted, and then they get a different color, but it's the same generic product. Could you design a survey to see which one of — what number of those people would be likely to raise a question or refuse to take it or raise a question with their physicians? Or would that be so hypothetical that it wouldn't be worthwhile?

In other words, one of the question I have to decide is to what extent would someone, if they saw a different color, raise a question with their pharmacists or doctors that they are not getting the same thing, and that it wouldn't have theraputically the same effect?

THE WITNESS: I think such a survey could be [Tr. 567] designed. I think that how passive it would be would be another question. But it's possible to design a survey where — and I am really giving you a very off the cuff reaction, that would involve the cooperation of a certain number of doctors and certain number of pharmacists.

The problem is that no doctor, or few doctors willingly call their judgment into question on the part of a patient. So if a patient — a doctor were worried about whether a patient believed there was a question with respect to the ingredients or the theraputic value, then the doctor might not want to cooperate in such a real life survey.

THE COURT: Let me ask you another question. Let's assume there are a great number of pharmacists out there who are not following the physicians orders, and where the physician puts down, dispense as written, signs on that line, as opposed to substitution permitted, in fact, in order to make an extra dollar or two he substitutes the generic drug, where the physician has told him not do [sic], and he gives him the same or what looks like the same blue capsule.

Would it be possible to take a survey to see how widespread that was?

[Tr. 568] Now, bear in mind in New York State they are violating the law, and maybe in some other states.

Take New York, for example, would that be possible to survey?

THE WITNESS: Yes.

* * *

[Taylor, Tr. 574] Q. Have you ever prescribed cyclospasmol or cyclandelate? A. No.

Q. Can you explain why not? A. I didn't think it helped.

Q. In your private and clinical practices have you [Tr. 575] ever treated a patient who was taking more than one medication? A. Yes.

Q. Why is that so? A. Well, very frequently a patient will have more than one disorder and so he would have to be given medication to handle the variety of symptoms.

Q. Is this particularly true of patients with nervous disorders or elderly patients?

THE COURT: That's two separate questions, isn't it?

MR. MARROW: Yes, I will separate them.

THE COURT: What can you say about elderly patients in that regard?

THE WITNESS: In general elderly patients tend to have more than one disgnosis and, therefore, tend to be placed on more than one medication.

THE COURT: How about those with nervous disorders?

THE WITNESS: They may have more than one, but it's not a given.

Q. Now, these patients who were taking more than one medication, were any of those suffering from senile dementia? A. I am sure some of them were, yes.

[Tr. 576] Q. And were some of those suffering from senile dementia and taking more than one medication self-medicating? A. If you mean by that that they were responsible to take their own pills, yes.

THE COURT: They take them at home, for example? A. Yes, they are responsible for the pills.

Q. Do you consider this a safe medical practice if a patient is disoriented, forgetful, et cetera? A. No.

Q. Did you continance or permit it? A. Very often you have no choice. If the patient lives alone and has no relative or close neighbor who would be responsible, you are stuck.

Q. Are there also degrees of senile dementia where it might be safe medical practice to permit self-medication? A. Yes, there are some patients who have it in mild form. Others are so severely disabled that you couldn't begin to let them do it.

Q. Now, would you say that there is such a danger that such a patient might take a medication on the wrong schedule? A. Yes.

Q. Do you recall any specific instances of that [Tr. 577] happening in your own practices? A. I can't recall of a specific instance, no.

Q. If such a thing were to happen would it create a danger to the patient? A. It certainly could.

Q. Are you familiar with any medical studies of patient compliance with instructions for taking prescription drugs? A. I am aware that many such studies have been done, yes.

Q. Is there a relative uniformity in their results? A. Yes. In general they have shown the patients not to take the pills as they have been directed.

Q. Have you ever treated a patient who kept more than one medication in the same bottle or pill box? A. Yes.

Q. Was this a common practice or an usual practice? A. Very common.

Q. Did you have a practice that you utilized in order to minimize the possibility of the self-medicating patient taking the wrong pill on the wrong schedule? A. I would sometimes try to suggest that they start [Tr. 578] in the morning and take out whatever pills are needed in the day from different bottles or sources, and then note that for that day they have perhaps four or five pills to take, and segregate those pills perhaps separately in another container; and hope in that way they would be at least correct for the day.

Q. Did you ever do anything to aid the patient aside from giving oral instructions regarding taking medication? A. I would very frequently write out a schedule as clearly as I could so they could pin it up somewhere.

Q. In your opinion do patients associate the color of medication with any particular aspect of taking that medication? A. Yes.

Q. And how does that come about? A. Well, they will say, "Oh, the red one is my heart pill," or something like that.

Q. Did you ever use the color of a pill in the course of your practice to aid the patient in identifying a schedule to take it? A. Yes, I did.

A. And how would you do that? A. Just as I said before. If he knew that the red [Tr. 579] pill was for the heart pill or the blue bill was the nerve pill, it would be helpful to me to be able to say, well, you are supposed to take the blue pill three times a day, or what have you.

Q. What is a maintenance drug, Doctor? A. It is a drug which the patient usually takes everyday in an effort to control certain symtoms, [sic] although one knows they may not secured by that means.

THE COURT: Over any particular period of time?

THE WITNESS: Yes. It could be any period of time.

Q. Well, if you are describing something as a maintenance drug, would that definition imply any certain extended period of time, or what? A. It certainly implies an extended period.

Q. Have you ever prescribed maintenance drugs in your practice? A. Yes.

Q. In your opinion do patients become accustomed to the appearance of such drugs? A. Yes, they do.

Q. Are maintenance drugs more generally taken by elderly patients than in young patients? A. In general, yes.

[Tr. 580] Q. In general, can you explain that. A. Since elderly people are prone to chronic diseases in which a maintenance drug is the only way of offerring them any help.

Q. In your experience, have elderly patients been more or less concerned about the price of drugs than younger patients? A. Elderly patients usually live on very restrictive income and are worried about the price.

Q. In your experience are elderly patients frequently concerned with the convenience of obtaining drugs, for example, from a nearby pharmacy? A. Yes, indeed.

Q. In your opinion, do patients rely upon the appearance of a drug product to insure themselves that they are receiving the proper medication? A. Yes they do frequently.

Q. And what is the basis of your opinion? A. The things that patients have said to me.

Q. Have you ever had the experience of treating a patient or a group of patients who continued to take the same drug in the same dosage form, but with differring [sic] appearance? A. Yes, I have.

[Tr. 581] Q. Could you explain to the Court the nature of your experience in that regard. A. Well, several years ago, I forget if it is eight or nine, maybe 10 now, a new drug came out for the treatment of Parkinson's disease, which is commonly known as L-D-O-P-A. It is an acronym.

Q. Do you know the actual name of the drug?

THE COURT: You don't need it. We all know Ldopa now. A. Originally when it came out it was made by a company, I forget who made it but it was very expensive. Patients were anxious to get it and they would pay I think between 50 and 75 cents a pill.

Q. For each pill? A. Yes.

Q. What did the pill look like? A. They were white and elongated.

Q. Was it a tablet or capsule? A. It was a tablet.

Q. Continue. A. And then a year or two later a short time later the patent elapsed and several other manufacturers began to make it. And also at the same time a process was discovered by which it could be made far more cheaply from [Tr. 582] vegetable plant sources rather than anomal sources, so that the price dropped. And from 60 or 75 cents, it was about 5 or 7 cents per tablet.

Then each of these manufacturers put it out under a brand name and everyone of the products had a different appearance.

Q. What was the patients' reaction? A. Frightened.

Q. I'm sorry? A. They were frightened. They didn't know it was the same drug because instead of being a white tablet, they were now getting pink capsules and green capsules and white round capsules, four or five different varieties and they had no way of knowing whether it was the same medication.

Q. Did they express their fright to you? A. Yes.

Q. Did you explain to them that the same drug was now being made in different appearances? A. Yes. I did try to explain it to them.

Q. What was the result of your explanation? A. Well, some patients accepted the explanation and they were glad that it was cheaper. And others did not feel happy with the explanation and elected to continue with the original drugs, if they could, although it was more [Tr. 583] expensive.

Q. Do you remember any specific instance of a patient going to great lengths to get the original product? A. Yes. I had one patient who was a retired dentist. And my practice was in Westchester County. When he originally started on the medicine I had him in the hospital in the Bronx. And he continued to drive down to the Bronx to fill his prescription, long after the substance was available more cheaply and in the neighborhood pharmacies.

Q. Doctor, have you ever had any emergency room experience? A. Yes.

Q. When was that? A. Intermittently, both while I was in training and, of course, while I was out in practice I would be called to emergency rooms.

Q. If a patient is brought into an emergency room suffering from an overdose of some drug, or whatever trauma it might be, is it important to identify the drug in the case of the overdose, or in the case of the trauma, whether the patient is taking a drug? A. Yes, it is very important.

[Tr. 584] And is the color — is the color or appearance of a drug sometimes used as an aid in identification for the drug? A. Yes, it is.

Q. Would you explain how that takes place? A. There are some drugs which are available in standard preparation for so very long that just by looking at the outside one could be certain that it contains the same material.

Q. Would there be any other factors that you would take into consideration besides the appearance of the drug? A. Of course, if the patient could tell me what they were taking, it obviously would help.

Q. Anything else? A. Call their physicians if they had one.

Q. Do you recall — what drug are you talking about or drugs? A. Simplest thing that comes to my mind is dilantin which is in a white capsule with a red back since Park-Davis brought it out. If you see that you're not in much doubt.

* * *

[Tr. 585] Q. Based upon your experience, do you have an opinion whether it would be desirable for all drug entities which contain the same active ingredients and have similar pharmalogical properties to be the same shape and color? A. Yes, I do.

Q. What is that opinion? A. I think that would be a very good idea for them all to be the same.

Q. Could you explain why? A. Because of the problem of knowing what is inside the drug, what is inside the tablet, there would be much less question in a confusing situation.

[Tr. 586] Q. Dr. Taylor, you stated that you changed your career in 1977 from private practice.

What did you change it to in 1977? A. I went into research and health care services.

Q. Can you describe what your work has been from 1977 until the time that you became associated with New York Health and Hospital Corporation? A. I spent six months at the Institute for Health Care Studies with the United Hospital Fund and then went to work for the federal government in what used to be called HEW in the Health Care Finance Administration Office of Research.

Q. Then you came to the Health and Hospital Corporation? A. Yes.

Q. Have you seen any private patients since 1977? A. No, I haven't.

Q. Have you treated any patients since 1977 private or otherwise? A. No.

* * *

[Tr. 589] Q. Did you ever prescribe librium? A. Yes.

Q. What is the generic name for librium, do you know? A. I am trying to remember. It escapes me.

[Tr. 590] Q. Do you know whether librium — whether a product similar to librium with the same active ingredient is sold by various generic companies? A. I am certainly not sure.

Q. You don't know? A. I don't know — chlordiazepoxide —

Q. Chlordiazepoxide? A. Yes.

* * *

[Tr. 591] Q. What is elavil? A. Amitryptilene.

Q. What color is that? A. Yellow and blue.

Q. Have you ever prescribed amitryptilene to be prescribed as a generic? A. Yes.

Q. Do you know the colors? A. No.

Q. Why did you not see the capsules? A. Unless the patient brought them in and complained, it wouldn't be necessary to see them. If they brought them in to complain, then the whole subject would be raised.

Q. I assume no one ever did that with amitryptilene? A. Not to my recollection.

Q. Do you have anything to do with the purchasing of drugs by the New York City Health and Hospital [Tr. 592] Corporation? A. No.

Q. Do you know how the corporation, in fact, purchases drugs? A. Yes.

Q. How does it, in fact, purchase the drugs? A. The corporation has an office of procurements who are responsible for obtaining the best prices paid on contracts and that is a complex operation which I can't describe, but the responsibilities of that office is to insure that they get the best possible price for a contract for whatever drugs the corporation buys. Individual hospitals, pharmacies, are then informed through various mechanisms, clerical letters, if they wish to buy some drugs or other, the contract has been let with a particular company, at a particular price, and since that is frequently a more advantageous price, a large percentage of the corporation's drugs are brought through these contracts, but the ordering is done at the level of the individual hospitals and these are all generic.

Q. Do you know in issuing these contracts the corporation changes suppliers from time to time? A. They are obliged to go out on bid and naturally if the previous supplier doesn't meet the [Tr. 593] requirements and the bid comes in from someone else at a lower price, they would change.

Q. You're saying they would take the cheapest price they could get as long as there is not a quality problem? A. They have their own standards and qualifications which must be met.

Q. Do you know if the Health and Hospital Corporation requires that medication be in a particular color? A. I have never heard of that.

Q. Now, I believe you stated in direct that you had had an experience with a color change in a drug for patients with Parkinson's disease? A. Yes.

Q. How many patients were involved? A. The change took place over the course of probably six months to a year and I saw several Parkinson patients every week, so I couldn't tell you precisely, but a fair number.

Q. When was that? A. This had to be in the early '70's.

Q. What are the symptoms of Parkinson's disease? A. The strongest symptom is a slowing down, [Tr. 594] inability to move properly, stiffness and difficulty in rising from position or change in position accompanied by a tremor and loss of capacity to demonstrate facial expression and there are others. Those are the common important ones.

Q. It is an extremely serious disease? A. Serious and disabling.

Q. Would you please tell us the extent of your emergency room experience? A. Well, during my training as a house officer there were regular rotation through the emergency room and of course I had four years of training. Then once I became a private practitioner I was on call to emergency rooms in hospitals where I had admitting privileges. So I was in and out of emergency rooms quite frequently.

Q. Could you tell us approximately how many instances — in how many instances you were present and called upon to treat a drug overdose in the emergency room? A. Yes, it would happen several times a year. I can't tell you exactly how many.

Q. What would be the first thing that you would do when a patient with a suspected drug overdose came into the hospital? A. After I took care of the patient's acute problem —

[Tr. 595] Q. What would be the first thing you did when a patient came into the emergency room? A. Examine the patient and take a history, if possible, find out what needed to be done to them to turn this thing around.

Q. Would it be essential that if there has been a drug overdose that it — for example, the stomach of the patient be pumped out? A. The first thing you do is to make sure the respiration is protected.

Q. About when you're checking the respiration, do you happen to know what drug he supposedly overdosed on? A. Yes. Different drugs can have different effects on the respiration, certainly.

Q. How would you determine at that point if someone has been brought into the emergency room what drug they were on? A. Sometimes the clinical examination will reveal that by the nature of the respiratory change.

Q. Do you know, Dr. Taylor, whether a patient could be on an antibiotic and antihypertensive medication at the same time? A. Yes, they could.

Could a patient be on an antibiotic and [Tr. 596] analgesic at the same time? A. Yes.

Q. Could a patient be taking an antibiotic and a product for the symtomatic of cough and cold at the same time? A. Yes.

Q. Could a patient take at the same time two or more of the following antianginal, antihistamine, and a drug for Parkinson's disease? A. Yes, because very often Parkinson's patients responded well to antihistamines so that was included in their treatment.

Q. I show you what I have marked as Plaintiff's Exhibit 122 this morning, Dr. Taylor, and ask you if a patient brought this into you, how you would identify the medication the patient was taking?

(Exhibit shown to the witness.)

A. Just looking at this looks like cynamede.

Q. Which are you talking about? A. The blue oval.

Q. Do you think they're all the same? A. The color is slightly different. There is a larger and small one, the larger one is lighter, MSD-647, smaller — I am getting middle-age, I need glasses.

[Tr. 597] THE COURT: Do you want to try mine?

THE WITNESS: Thank you.

A. Says Stewart and it has no number on it.

Q. Would you rely on color to distinguish the medication that this patient has brought in — this hypothetical patient? A. Color is very, very helpful, yes. For the rest I would have to rely on the name and their product, number —

Q. Why? A. Because I can't tell from what is in them. They could be anything. I would have to look them up. That would be true of all these that have names and numbers and I would go to the PDR in the product identification section.

* * *

[Tr. 599] Q. Are you aware, Dr. Taylor, that there are generic drugs on the market today that are not in the identical color of the drug first manufactured under patent? A. Yes.

Q. Do you know how frequently that situation, in fact, exists? A. No, I don't.

Q. Is it your testimony — your testimony was, I believe, that you didn't think it was a good idea to have the same drug in different colors; is that correct? A. No.

Q. This is your opinion, not a reflect of what actually exists in the marketplace; is that correct? A. Yes, my opinion is that the drugs should be the same color, right.

Q. Have you ever prescribed any kind of vasodilators. A. On occasion I used to prescribe some of the papaverine derivatives.

Q. Do you know which of the papaverine derivatives? A. That I prescribed generically, I don't remember the brand name.

Q. Do you know if it is available from several manufacturers in different colors? [Tr. 600] A. I don't know. I imagine it is, but I don't know.

* * *

[Gatty, Tr. 606] Q. Having reviewed those documents and exhibits 74 and 75, can you state your opinion as to whether it is possible to make a statistical meaningful projection to the population of doctors who prescribed cyclospasmol from the results of the survey? A. No, I don't think it is possible.

Q. Do you — could you state firstly in broad general terms without getting into details for each one, the reasons for your opinion? A. Well, the first one is the extremely low response rate.

Q. What is a response rate? A. Well, it is the percentage of people who have replied as a percentage of those one tried to contact.

Under probability sampling, when we select a target sample we are obliged to take interviews of those people designated, designated objectively.

A sample of successful completion is very low.

Q. What was the percentage of completion or reasponse [sic] rate in this case. [Tr. 607] A. I see it as 20 percent. I believe 169 out of 580.

* * *

[Tr. 626] THE COURT: I see. How do you know that 80 percent of them will, unless you have gone through the whole process?

THE WITNESS: No, because theoretically we know from the normal curve —

THE COURT: Now tell us what that is.

THE WITNESS: It is one mathematical form of symetric bell curve in which suggests to us that these estimates will, most of them, fall in a distribution mainly about the true value, but we'll get some extremely high or extremely low.

THE COURT: Doesn't that depend upon the subject that you're after? The shape of the curve will that not depend upon what you're trying to find out and the subject matter that you're after?

THE WITNESS: No, your Honor. In general we find that the normal curve describes many natural phenomena. When it does not we can make [Tr. 627] mathematical transformation which will make it behave, so we can treat it in this way.

* * *

[Tr. 628] Q. Let me ask you a question. If you wanted to be right 80 percent of the time, what would happen to these confidence limits around the 24 percent and the 29 percent? A. If one is satisfied with 80 percent confidence one gets very wide — one gets reasonably narrow limits. If you make a more stringent requirement on the confidence what happens it becomes very wide.

Q. If you wanted to be right 95 percent of the time, you'd have to increase the limits around your result in order to encompass that 95 percent figure; is that correct? A. That is correct. I would look to the layman as if it were less accurate study. That is what we're getting from using an 80 percent confidence, in my opinion, a deceptive appearance of accuracy.

* * *

[Tr. 640] Q. Did you read the pharmacists — A. Yes.

Q. Do you have any comments as to that? A. First, the first impression I had was that it was sort of winged casually and I imagine that Dr. Lipstein was not called in until after it was done, because the — the using of two sources in the sampling —

Q. One was the Ives list and one was the Hayes list? A. Correct. — is most unusual. It really means to me that some non-professional began doing the study and — it was my impression that perhaps a professional was brought in, but I think what ought to have been done was to chuck out the first half of that and stick with the Hayes directory.

Q. Is there any justification of combining the two surveys, the Hayes directory pharmacists and those of the Ives list pharmacies? [Tr. 641] A. One has not detected a difference does not mean that a difference exists. Especially with much small samples where one is not likely to detect differences.

* * *

Q. What is the general practice in describing percentages to figures of this nature, Dr. Gatty? A. To start with I think it is not at all appropriate.

Q. Why? [Tr. 642] A. To use percentage figures when you have less than a base of 100. What we're talking about, for instance, four people here seem to be labeled 33 percent. That is, it seems to inflate it when you use two digits to represent a one digit number. So I would criticize that very sharply. It gives a false sense of accuracy which is not in the data.

Those percents are computed from the basis of subsamples and that seems in itself to be inflating of these percentages quite a bit.

For example, if we take on the last table of that report, the ten percent in the lower part of the table, cyclandelate dispensed and labled as cyclospasmol — it is ten people, that is given as 29 percent.

It seems to me much more appropriate to say that those ten people are taken out of 83 which is 12 percent. What we have is the figures engineered with their basis to inflate them in a way that could be misleading.

There are other points such as — which are perhaps minor that the two samples combined are inappropriate for another couple of points of view. One is that one of them is a simple random sample and the other is a cluster sample.

We have confused the precision of this. I [Tr. 643] think those are the main points.

* * *

[Sperber, Tr. 655] Q. When offering national-brand products for sale, what procedure have you followed as far as describing the product, and please tell the court your reasons. A. You said when offering national brands?

Q. Yes. A. When we offer a national brand product we merely list it in a complete catalog with the name of the product, sometimes the name of the manufacturer and our [Tr. 656] selling price.

Q. Would you compare this with the technique you utilize when you offer a generic drug for sale? A. Yes.

When we offer a generic preparation, just the mere mention of the name of the generic name would be meaningless to many, many of our customers.

We therefore have to qualify that with a reference to the proprietary product.

In fact, within the last number of years the Food & Drug Administration has issued a regulation which requires all of the major brand manufacturers, including Ives, to list right on the label, and in all of their advertising to the profession.

And they even specify the size of the type, the actual generic name of the product.

And the reason this came about is because the population —

MS. DRISCOLL: I object for his giving reasons.

THE COURT: Is that in their report, what reason they gave?

THE WITNESS: I don't know if it is in their report.

But it is the reason we choose to market [Tr. 657] the product the way we do.

Why do you choose to market it that way?

THE WITNESS: Because the physician and the pharmacist, especially the ones that went to school when I did, 25 years ago, only know the product by the way in which the company details the product.

Ives does not use the name cyclandelate, they only use the name cyclospasmol.

Q. You made reference to the fact that you are referring a generic product to a branded product.

Is this what is known as comparative advertising? A. Yes, it is.

Q. Do generic drug companies detail their products? A. Do generic drug companies detail their product?

Q. Yes. A. No.

We generally are selling products at what we call generic price.

And we don't have the advertising budget allowances to be able to afford detailing our product.

[Tr. 658] Q. Do you receive catalogs from generic drug manufacturers now as distinct from distributors who are offering their products for sale? A. Yes, we do.

Q. Generally do the generic drug manufacturers in their catalog use comparative drug advertising? A. Yes.

Q. And do you have an opinion what would happen if the generic drug manufacturers who offer their products for sale to you do not use comparative advertising with reference to the generic drug products they are offering for sale?

* * *

THE COURT: * * *

How do you define comparative advertising?

THE WITNESS: That is when I would take the generic name of the product and compare it to the branded product.

For example, we would in our catalog, we have a table where we would list the proprietary and national advertised brand on one side, and on the other side we would list the company brand [Tr. 659] product by its generic name or the name we sell it under.

THE COURT: What does a column with the generic name, what is it headed by?

THE WITNESS: Schein generic name or generic name.

THE COURT: Now, do you have an opinion on the question that was asked of you, suppose they didn't use comparative advertising?

THE WITNESS: Thank you.

Q. I am talking about generic drug companies who manufacture products which are offered to your company, the distributor. A. In my own personal case I am very much abreast of all the generic names.

I know for example though that many others in businesses akin to ours would not know what they are talking about unless they use the comparison.

* * *

[Tr. 664] Q. Mr. Sperber, in your opinion, would the pharmacist that receives your catalogues have any problem telling which is the generic product and which is the branded product?

* * *

A. The pharmacist for years has been detailed and sold the major brand products and he knows that dynoxin, the very first one, is a Leatherly product. He should have no problem identifying which is the generic and which is the branded.

THE COURT: Who determined these generic names?

THE WITNESS: That is part of the problem. The generic name is a name that is designated by [Tr. 665] some governmental body — scientific panel.

THE COURT: All right.

Do they make them up or is there some scientific — I suppose they must make them up like a digestant would seem to be kind of a —

THE WITNESS: It has some connection with the actual chemical nomenclature, but it is not truly the chemical nomenclature. If you look on page 808, chlorpheniramine, that is, I believe, the actual chemical name of that product. It has been chosen for the generical name. It is a cumbersome name to be used and that is why the major companies choose to promote it.

Q. Mr. Sperber, do you have an opinion as to whether a pharmacist who receives your catalogue which contains comparative advertising would be encouraged to illegally substitute in filling a prescription?

MS. DRISCOLL: Objection.

THE COURT: I will let him answer.

A. I have an opinion, and that is if the pharmacist is a law-abiding citizen and practicing his profession in the proper manner he would have no problem at all.

THE COURT: Let's put another question, though.

[Tr. 666] Let's assume that he's not so great. He has a little bit of larceny in his soul, and he sees this list.

Wouldn't that make it easier for him to do that?

THE WITNESS: Yes, it would make it easier for him, but by the same token it would deprive 99. some percent of the law-abiding pharmacists —

THE COURT: That really wasn't my question.

THE WITNESS: Okay, I felt that I had to get —

THE COURT: You don't have to get anything in. Mr. Cobrin will ask you any questions that he wants.

Q. Mr. Sperber, do you have an opinion as to whether a pharmacist would be more familiar with the name of a branded product or the generic name of the product?

MS. DRISCOLL: Objection.

THE COURT: Overruled.

A. Yes, obviously the pharmacists would be familiar with the name of the branded product until a product goes off patent which is 17 years, nobody ever trys to get across to him the generic name. There is no reason for it. When Ives details or promotes their product they promote cyclospasmol they never promote the name cyclandelate. It has only in the last couple of years that they had to use the name on the label.

[Tr. 667] THE COURT: Are mostof these drugs where there are generic lower priced generic equivalents, have they been patented, do you know?

THE WITNESS: Originally, yes, but now the patents have expired.

Q. Do you have an opinion as to whether generic drugs or the corresponding branded drugs are more expensive to the consumer? A. By far branded drugs are more expensive.

Q. Have you ever received, and I am referring to you now as Henry Scheine complaints about the appearance of your generic drugs, vis-a-vis, the appearance of the corresponding branded drugs? A. Yes, I have.

Q. Could you tell the Court about them? A. We purchase our generic products from a number of different contract manufacturers, and it is our intention to have the product as closely as possible duplicated in appearance of the national advertised brand. But sometimes the colors between different manufacturers get a little slightly off and every now and then when we purchase, for example — well, every now and then when we purchase a product from multiple manufacturers and the color does vary slightly a pharmacist does complain to us that he has [Tr. 668] problems in explaining to his patients why it was a slightly different shade of yellow this time that it was on a previous prescription.

* * *

BY MR. MARROW:

Q. What would result if your catalogue did not contain the names of the branded product and only contained names and prices of generic products? A. I think it would result in much confusion on the part of the customers because they wouldn't know what the products were comparable to and it would obviously result in lower sales by us.

[Gringauz, Tr. 684] Q. Have you ever had a patient in your years of dispensing pharmaceutical products inquire as to who the manufacturer of prescription drugs are? A. Not a lay patient. They are not really concerned with who makes the drugs.

Q. Do you have an opinion based on your years of pharmaceutical experience as to what the function of color is to the patient as to the medicine he or she might take?

* * *

A. Based on my years of experience I have come to believe that the patient identifies the color and the same of the medication with a disease, such as a blue tablet for their high blood pressure, a white one for their heart.

And not only that they seem to associate this color of medication with the time of day.

THE COURT: What do you mean by that?

THE WITNESS: By that, they have the idea that they take their blue tablet at 9:00.

In other words, it not only is the association [Tr. 685] of the color and the size with a disease, but also there is a correlation with the time of day as to the frequency of administration of their medication.

Q. In your experience as a pharmacist have you seen patients comingle a daily regimen of pharmaceutical products they are supposed to take in a single vial? A. Oh, yes.

Q. Do you consider this to be a good practice? A. Absolutely not.

Q. Do you know how these patients determine which medication to take at particular times? A. In their mind they have their dosage regulated. It is a correlation between color and dosage.

For example as I said before the blue tablet they would take at 10:00 in the morning.

The red one they would take at three in the afternoon.

So quote often they have a vial in the hospital when they are admitted, and the nurse comes down tomorrow with a vial, and ten different colored capsules are in there, and they know that this particular capsule they take at a particular time.

THE COURT: Or think they know.

[Tr. 686] THE WITNESS: Yes, your Honor.

This is what they have been doing for years. I am talking first about the patient taking medication for chronic illness as opposed to Ambacute or Ampicillin or some kind of antibiotic. This is an association with the disease as well as with the time.

Q. Have you ever personally been involved in dispensing a generic non-look-alike to a patient who had previously taken a corresponding branded drug having a different appearance? A. Oh, yes.

MR. COBRIN: We have a number of pills, your Honor, if you like I would hand them to you as well as to the witness.

* * *

Q. You have in front of you Premo Exhibit 13, which is Apresolin, 50 miligrams Ciba. A. Yes.

Q. What is the active ingredient there? A. Hydrochlorzine.

Q. So that it is clear, what would be the color? [Tr. 687] A. This is a blue tablet.

* * *

Q. I take it you have in front of you Premo Exhibit 14, which is hydralazene, 50 miligrams Lederle. A. Yes.

Q. What is the color of that? A. Pink.

Q. Have you ever personally dispensed Lederle hydralazene to patients, and I am talking about 50 miligrams to patients who had previously taken Ciba Gygees Apresoline? A. Yes.

Q. What had happened? A. The patient was very apprehensive. Sometimes the patient refused the medication and preferred the blue tablet.

Sometimes I was able to explain to them that it was the same by another company.

Q. What did you do in a situation where the patient insisted on taking the blue tablet? A. I explained to them that the only blue tablets I had were the 25 miligram.

[Tr. 688] And the patient was very happy if I would give them the 25 miligram [sic].

But the ironic thing is that the 25 miligram [sic] tablet which was blue, and I would like to point it out here, was also made by the same company, Lederle.

And in essence it just made him fell better. But it was the same company and it was just a different color.

Because Lederle for some reason makes a 25 miligram [sic] generic blue, and they make a 50 miligram [sic] generic pink.

THE COURT: So you gave him or her two blues?

THE WITNESS: Yes, but not what — in other words, they wanted the blue thinking that they would receive the Ciba.

THE COURT: I understand.

Q. Have you ever had problems — have you ever been involved in a situation where there was a generic non-look-alike for a patient who had previously taken a branded product of a different appearance where the patient was a Russian immigrant? A. Yes, quite often.

Q. What do you do in a situation like that? A. Not only Russian, we also have Spanish-[Tr. 689]speaking people.

And it is rather difficult, to say the least, because I cannot explain to them that this is the same drug that they perhaps received last month that was a different color.

And in all honesty, all I do is fill the prescriptions and put them in a bag and give them the medication, and hope when they go home that they will take it.

I don't know whether they understand it is the same drug that was a different color last month, or if they feel perhaps that the doctor changed the strength or the medication, but it is totally out of my hands.

I give them the medication and hope for the best.

MR. COBRIN: Mr Trost, would you hand the witness, please, Exhibit 15, which is Antivert, 25 miligrams [sic] Roerig.

Q. What is the active ingredient in that, if you know? A. Mequizine.

And what is the color? A. This is a yellow on one side and white on [Tr. 690] the other.

It is an oval shape.

MR. COBRIN: Would you hand the witness, please, Exhibit 18, which is Mequizine hydrochloride, 25 miligrams [sic] Lederle.

* * *

Q. Would you compare the color of 18 to 15? A. This is yellow through and through. It is not a two-color medication.

Q. This is 18? A. 18.

Q. Have you ever dispensed Lederle's Mequizine to patients who had taken Roerig Antivert, and I am talking about the 25 miligram [sic] dosate [sic] strength? A. Yes.

[Tr. 691] Q. And what is happening? A. Apprehension, I would say, and anxiety, some of the time.

Sometime they will take the medication and get home and just call me and ask me if it is the same medication.

I seem to have a less difficult time with this particular tablet because of the shape. It is a characteristic shape.

And half of it is the right color which allays some of the fears.

It is just if they turn it over, they don't see the white, and I think it's a 50-50 chance, for some reason it makes them a little more confident that it is the right drug, and most of it is similar to the drug that they have been taking, the shape and the color.

MR. COBRIN: Would you give the witness Exhibit 16, which is Antivert .5 miligrams [sic] Roerig.

[Tr. 692] Q. Have you dispensed that drug? A. Yes.

Q. What is the active ingredient in that? A. Also meclizine.

MR. COBRIN: Could you hand Exhibit 17, which is meclizine, Lederle, 12.5 to the witness? A. This is totally blue.

Q. When you say this — A. This is number 17.

Q. What is the color of 16? A. 16 is a blue and a white layer. That is the trade color. The generic is all blue.

Q. Have you ever dispensed meclizine by Lederle 12.5 to people who have taken roarax 12.5? Yes.

Q. What happened? A. A similar situation. There is anxiety, apprehension. It is much easier to explain to the patient. They accepted it a little more frequently.

Q. Ives isordil sublingual 2.5 by Ives, what is the color of that? A. Yellow.

[Tr. 693] Q. 52B, Stuart sorbitrate sublingual 2.5 —

* * *

Q. What is the active ingredient in A as compared to B? A. Exactly the same.

Q. Have you dispensed Exhibit 52B — what I mean is, the drug of 52B to patients who had taken 52A? A. Yes.

Q. What happened? A. I think the patient — I am not really sure — I can't tell you. They have this blank look on their face when you explain to them it is the same drug by another company. It is just a different color. I have the feeling that they are rather apprehensive about the situation.

Q. 53A, you have 53A in front of you, which is isordil oral five milligrams.

What is the color of that? A. Pink.

Q. And 53B by Stuart sorbitrate oral five milligrams? A. Yes.

Q. Could you compare for the Court the active —

THE COURT: What is the color of that?

[Tr. 694] THE WITNESS: It is not only a different color, it is a different shape. It's green and it is oval in shape.

Q. Would you compare the active ingredients in 63A and B? A. The same, isozorbic dyanytric.

Q. Did you ever dispense Stuart's to a patient who has taken Ives? A. Yes.

Q. What happened? A. I get a blank stare some of the time and I have a feeling there again, I can't tell you what they're feeling inside. I try to go out and explain to them that it is the same drug by an equally good company and it is just a different shape and a different color.

Q. In connection with your telling patients that they're getting the same drug only with a different appearance, have you done this with people who are 65 and older? A. Yes.

Q. Do you have an opinion as to how these people who are 65 and older reacted to your representation as compared to people who are younger, say in their 40's, 30's? [Tr. 695] A. By in large the elderly patient is much more apprehensive about their medication, maybe because they're taking it longer, maybe because they have been around a little longer. When they're used to a particular color medication for many years it is very difficult for them to accept the fact that it is a different color that it is the same drug.

Q. Have you ever been involved in a situation involving emergency treatment of a patient suspected of having an overdose wherein the appearance of the tablet is available and it was desired to learn what it was? A. It has happened several times.

Q. Could you tell the Court the most recent experience that you had? A. The most recent experience I had about two weeks ago. The emergency room doctor brought down to me a prescription vial which had been filled in the community pharmacy. The pharmacist had taken a shelf packet of a medication from the shelf and on the back it says acetominophen, which is tylenol.

In filling the prescription he wrote — he had the label and labeled it aspirin. So the child actually had an overdose on this which was lethal and the treament of both drugs are completely different.

[Tr. 696] The emergency room doctor brought the vial down to me. There were a few tablets left and he said, "What is it?" Is it really tylenol or aspirin?"

Well, I couldn't a hundred percent say what it was since the fact that tylenol by characteristics of the shape of it usually generic manufacturers make the tablet flat and level on the edges to resemble tylenol. Aspirin looks more rounded.

I told the doctor I could not conclude one hundred percent what it was. Based on the looks of the medication if I had to make an educated case, I would definitely go for the fact that the child had an overdose on the tylenol.

The doctor had really nothing else to go by on that, except at that point. So since the antidote for tylenol was relatively innocuous, you have to start it early, and hope that it was tylenol and later on the blood tests did confirm it was.

And I feel in this case and really any other case it has disadvantages for things to look alike that the emergency room doctors need something to go by.

* * *

[Tr. 698] Q. Is there a problem with look-alikes or non-look-alikes in antibiotics?

* * *

A. Actually if you received an antibiotic one day from a doctor and say it is amplicillin and next year the doctor gives you another prescription and it is a [Tr. 699] different color, the patient doesn't care if it is the same color as long as it works. It is not like with the elderly patient, the chronic patient, for their blood pressure, diabetes, the colors are important because they come to identify it as being right.

It may not be right or wrong, but in their mind this particular color is right and if it is right for them it somehow works.

Q. Mrs. Gringauz, do you have an opinion as to whether or not it is desirable to have generic drugs as look-alikes of corresponded branded drugs? A. Definitely. I wouldn't be here otherwise. I really feel —

Q. What is the basis of your opinion? A. It is primarily as a pharmacist. I am the last line person between that medication and that patient and we — you have to have confidence in the patient — they have to have confidence in you as well as in the medication at that time.

Now, I hand the patient a medication and they think I made a mistake. Even if I didn't make a mistake, sometimes psychologically they won't take it. If they do they swear it doesn't work. They have to feel it works. The patient becomes anxious and apprehensive if it is not [Tr. 700] something that they recognize is right.

I think the patient has to have some control over their destiny. Now, if they're used to a white tablet or a yellow tablet, if they don't get that yellow tablet, they have a right to question, am I getting the right drug, because I tell you sometimes they don't get the right drug. It is not automatically the patient's fault. I must confess that pharmacists make mistakes like anybody else. Not only that doctors make a mistake when sometimes they're in a hurry when they write a strength it might be in a different color, and the patient says, why am I getting white now since I had yellow.

I listen to them. You must listen to them. They're not all stupid. They know what they're talking about. They have a right to know. They have a right to question.

* * *

[Tr. 702] Q. Does competitive bidding enter into the purchasing at any stage? A. Yes.

Q. At what stage does it enter? A. Competitive bidding enters into the stage probably at two leves [sic]. I don't know if you're familiar with the Joint Purchasing contracts. It is a buying group — it is a buying group that sends out bids to competitive vendors for a generic drug. They'll get a bid and usually they'll award a contract to a vendor. This vendor gives a contract number. We are not bound by it. Usually they have good prices. They'll be awared [sic] the JPC contract for a particular item. It behooves me to buy from that vendor.

Now, some companies do not go along. They do not submit bids to Joint Purchasing in which case St. Johns independently goes to different vendors and asks them for contracts based on a yearly volume of the three hospitals that are a part of the charities. We get our own contracts

* * *

[Tr. 703] through the companies directly.

Q. Have you ever rejected a drug product because of its appearance — a drug product provided by your Joint Purchaser? A. I never had to.

Q. Now, in your pharmacy, do you stock amitryptilene? A. I do.

Q. In how many colors? A. We don't use that many psychotrophic drugs. On that we probably have the orange by Roche.

Q. Do you have a generic also? A. By generic I don't know if you consider that generic. Roche is a big outfit. If you consider the generic, fine, I do. The original was a different company and in a different color. It is a generic even though it is a very, very, fine house.

Q. Do you also buy amitryptilene from another source other than Roche? A. First of all, we don't use many, so we don't.

Q. Do you recall having testified in this case at a deposition?

* * *

[Tr. 704] THE WITNESS: I remember, yes.

Q. Did you not testify that you had also purchased amitryptilene from Merck? A. I said we had some Merck on the shelf.

Q. How did it get there? A. It may have been there from a long time ago because we do not use much of this particular product. I think it was there before the Joint Purchasing contract was awarded to Roche which must have been a couple of years ago.

Q. But the Merck product was a different color from the Roche product, correct? A. I am sure it is.

Q. Do you stock imipramine in your pharmacy? A. Yes.

Q. Have you purchased imipramine from more than one source? A. I have purchased imipramine from United States Vitamin. We do not use it. Many drugs of this particular nature, that is why I say there are some on the shelf but I do not purchase it because it was purchased before the awarding of the contract to United States Vitamin.

Q. Is the color of the imipramine sold by United States Vitamin different from the color of the tovernil on the shelf? [Tr. 705] A. I am sure.

Q. Either amitryptilene or imipramine an antibiotic? A. No.

Q. Have you ever received any inquiries in connection with either of those drugs about the color of the particular drug dispensed, given the fact that this happens rarely? Have you ever received any inquiries? A. The imipramine that we'd use would be used in-house for the patients in-house, if at all. If the patient were on a similar drug on the outside and they came in for a different problem, may have come in for a medical problem. They happen to be on the psychotrophic drug secondary to another disease. The clinics that I fill prescriptions for are basically medical clinics. They're not psychiatric clinics.

I do not fill prescriptions for imipramine. I have not in an out-patient situation — I can't remember probably because I can't remember ever having filled prescriptions for my out-patient prescriptions.

Q. Can you ever remember a problem in an in-patient situation? A. Not specifically at this moment.

Q. Do you also carry in your pharmacy more than [Tr. 706] isozorbic dyanytric? A. Yes.

Q. And of ampicillin? A. Yes.

Q. Tetracycline? A. Yes.

Q. Doxicycline? A. Yes.

Q. And hydracyline? A. Yes.

Q. Now, what percentage of the prescriptions that you dispense are out-patient as opposed to in-patient in the hospital? A. I personally fill —

Q. The pharmacy. A. — or the pharmacy. We fill beteen [sic] ten to twelve thousand prescriptions per month. On the out-patient we fill about — at least five hundred a week. That is a hundred a day, five days a week.

THE COURT: That would be about 2,000 a month?

* * *

[Tr. 707] Q. How many prescriptions do you personally fill per week? A. Between 150 and 200, I would say. About 30 a day minimum. Between 150 to 200 out-patients.

Q. You personally? A. Me personally.

Q. Have you ever had any inquiries about the color or change in color of isozorbic dyantric, ampicillin, tetracycline or doxicycline? A. Yes.

Q. And on what occasions? A. Which drug?

Q. Which drug have you had an inquiry? A. Ampicillin and isovdil.

Q. Can you please describe what transpired when [Tr. 708] the inquiry was made? A. Let's take the ampicillin. It is on an out-patient basis. Normally I don't have problems with an antibiotic on an out-patient.

One specific instance comes to mind. We have an emergency room which is open 24 hours a day. During the night when the pharmacy is closed we dispense to the emergency room the unit dose capsules which is by one vendor. The emergency room will give out to the patient three or four capsules and say to the patient, "You take these now, here is the prescription. You come back in the morning and get it filled."

The emergency room doctor gives the patient four ampicillin capsules in unit of use which is one vendor.

Q. Excuse me, unit of use? A. Unit of use.

Q. What is that? A. It is if an ampicillin capsule is individually wrapped it can be referred to as unit or unit dose. It may have the vendor's name on it, the expiration date. It is what we use for in-patients which is one vendor. The emergency room operator gave the four capsules to the patient and says, "Come back in the morning and get the prescription filled."

[Tr. 709] They come back in the morning and hand me the prescription and I fill the prescription for 28 ampicillin and the patient walks ten steps down and says, "You gave me the wrong thing."

Q. What did you say? A. I never disallow what the patient says. I went and looked at the prescription to see if it was ampicillin, and it was, so I didn't give the wrong thing.

Q. What did you say? A. I said, "What do you mean? Why did I gave you the wrong thing?"

The patient says, "Well, the doctor told me last night that you will give me the same thing what he gave me and this isn't the same."

I had to dig a little further into the situation to see that the ampicillin capsules that were given at night were given in the unit of use from a contract of one vendor.

I explained that to her and I think I got it across. You never really know. I think I did.

Q. Now, in connection with in-patients at the hospital, have you ever had occasion when a nurse has made an inquiry to you about the color of a product that you have dispensed for in-patient use? A. Yes.

* * *

[Tr. 710] Q. Now, if these patients were given a different color product because it was, in fact, a different drug, would they not in those situations also question whether you had given them the correct thing and could you explain to them in those instances? A. Yes.

Q. How would you explain to them in those instances? A. Well, as I said before, if it is a different [Tr. 711] color and if I don't call it to their attention first and they ask me, "Is this the right medication —" let's say that I give them a yellow tablet and they're used to a white tablet, I would try to check into it. I would see if there is a similar product or the same product in a different strength. Tetracycline which is an important medication for the chronically ill, it is not uncommon for a patient to say that I am used to getting it white, why the yellow.

When they say this to me, I double-check to see if there is a mistake made. I think this is a positive thing.

* * *

[Tr. 716] Q. How would you fill a prescription that said dispense as written? A. Today or then?

Q. Today. A. That happens to be a very nice question, because it happens on who has the money to pay for it.

If you have money to pay for the prescription and if the doctor writes on the prescription, dispense as written, you as a patient are very fortunate, you can get the same color every month.

If you are on Medicaid and the doctor writes dispense as written, unfortunately, this is not the case.

The patient gets the generic.

Q. I asked how you would dispense a product if it says dispense as written. A. It depends on whether you are going to pay for it out of your pocket or if the Medicaid is going to pay for it.

That is what I am trying to explain.

* * *

[Bloom, Tr. 733] Q. Doctor, what is the usual duration of use by a patient of Cyclospasmol, and could you explain your answer to the Court, please. A. The drug is often used in a long term chronic situation where the problem will be existent for a long time.

Q. Are you familiar with the expression "maintenance drug"? [Tr. 734] A. Yes.

Q. Is this considered to be a maintenance drug? A. In a broad sense that you are speaking of drugs that are used over a long period of time, yes.

Q. In your practice do you prescribe drugs for patients? A. Yes.

Q. Do you tell your patients anything about the appearance of the drugs when you prescribe them? And could you explain to the Court what happens? A. I frequently will describe the medication I am prescribing to the patient, telling them certainly about how often to take it, when to take the drug, what the drug specifically is for, and frequently what the drug looks like.

The latter part is important to many patients who are quite elderly or have difficulty in identifying specific medications.

Q. Do you have an opinion — strike that.

How long have you been a physician? A. My licensing in the State of New York has been 16 years.

Q. Do you have an opinion based on your years of experience as a practicing physician whether it is desirable from a medical standpoint for generic cyclandelate to be in [Tr. 734A] the same colors, size and shape of cyclospasmol? A. In a general sense I think that all drugs, specific drugs for a specific purpose should look exactly the same.

[Tr. 735] Q. Why is that? A. Well, it avoids the confusion that patients often have. They may, because of the dispensing, receive what is exactly the same medication, but it looks differently. This has happened and has often caused a great deal of confusion and anxiety on the part of the patient.

Q. I forgot to ask you this question, Doctor.

When you prescribe cyclospasmol, on the prescription blank, which line do you sign? A. For almost all drugs I sign substitution permissible.

Q. Have you ever in the past received inquiries from your patients who were receiving generic medication which had an appearance different from the corresponding branded medication they had previously taken. A. I have received inquiries from patients who tell me that the medication they have just got is different from the medication they were previously taking or supposedly the same condition. And the answer is yes.

Q. Have you ever had a patient refuse to accept medication that was in a different appearance from that which he had previously taken? A. That she had previously taken, yes.

Q. She had previously taken? [Tr. 736] A. Yes.

Q. And which medication is that? A. The specific medication Isososorbide.

Q. Have you received, other than this lady, I take it, inquiries from patients who had received generic drugs that were not look alikes of corresponding branded drugs? A. Yes.

Q. Generally what is the nature of those inquiries? A. Well, the patient would call and tell you that he thinks the pharmacist made a mistake because the druge [sic] he got, the new prescription is different from the one he had previously taken.

Q. Based on your years of medical practice, do you have an opinion as to what function the appearance of a medication serves for a patient?

* * *

A. I feel that most patients use the shape, size, the color and other such things as identifying the specific use of the medicine. They may not know the name of the medicine but they know that this pill is for diabetes and that pill is for their heart, so they associate specific characteristics of each pill with a certain kind of condition that they have.

[Tr. 737] Q. Doctor, have you ever prescribed a medication to a patient that had already been on a number of other drugs? A. Yes, frequently.

* * *

Q. Can you explain to the Court what information you would give to such a patient, and if you like, I will hand you Premo Exhibit 51.

* * *

THE WITNESS: Frequently when there is an elderly patient with a large number of different medications, where there is quite likely to be confusion as to the drug to take, the time of the day to take it and such, I will instruct the patient about the new medication I am giving him, as to its nature. I might say this is a diabetic pill. It is a big white round tablet. You take it in the morning or evening with or without meals.

The kind of questions the patient asks you, should I take it with orange juice or water, et cetera.

[Tr. 738] At times it's not sufficient to get the patient on the proper regiment. And when I identify such a problem, I often make up a card, such as an example which has been presented.

THE COURT: That's Premo Exhibit 51?

THE WITNESS: Yes.

* * *

THE WITNESS: Which has information as to how you take the pill, the name of the pill, both the trade name and the chemical name. When you take the pill, dosage of the pill. There are often two pills thay may look very similar and have different dosages. And I have also used a pill stapled to the card as a further identifying methodology.

Q. Do you explain the appearance of the pill to the patient? A. Yes. I tell them he is receiving a specific pill. I try to characterize it by its size, shape, color, any special unusual things. Some pills have flattened bottoms. There is a diabetic pill with such a description.

Q. Is Exhibit 51 a duplicate of a card made for a patient? A. Yes.

Q. What was the condition of that patient? A. This patient had a combination of a diabetic, [Tr. 739] hypertensive and arteriosclerotic heart disease.

Q. Do some of your patients, Doctor, take different medication on a daily basis and self-medicate? A. They always, almost always do.

Q. Do some of your patients who take different medication on a daily basis who self-medicate comingle their medication in a single vial? A. Yes, I would suspect that they do.

Q. Do you consider it to be a practice that you endorse? A. No, I do not endorse that they mingle the pills.

Q. How do these patients who mingle the pills decide what they take when?

MS. DRISCOLL: Objection.

THE COURT: No.

A. They have told me that they know it by the color, the form, the size of the pill.

THE COURT: I take it there is no generic for the last drug on Exhibit 51 which has a Ciba name on it.

THE WITNESS: There are other pills that do exactly the same thing and have the same composition.

Q. But you wanted this patient to have Ciba one? [Tr. 740] A. I wanted to give him the pill.

* * *

[Tr. 740] Q. Do you have an opinion as to whether or not a [Tr. 741] person who is considered to be more elderly might or might not suffer anxiety if they were taking a branded medication and were switched to the generic medication having the same active ingredient, only a different appearance? A. Well, in this specific instance I alluded to before, the patient was very disturbed about the change in what she thought was a different pill. And eventually I had to put her back onto a pill with a different mode of operation. Instead of under the tongue, she had to take it by mouth swallowing.

Q. Doctor, have you ever used the appearance of a drug for identification purposes? A. Yes.

Q. Could you just briefly explain that to the Court. A. At times patients will come to you who have already — these patients are already on other medication, given to them by another physician. And they often don't know the name, the specific name of the medication, but they can describe it. It is a small white pill used for my heart, or a big red pill used for something else.

And you may use this as a basis for attempting to identify the pill.

Also, it is a sort of a clue that the specific [Tr. 742] pill, you can show him the pill perhaps if you have it available or you can use the physician's desk reference, which has not all the pills, but a good number of pills in there reproduced. And you can show it to the patient and he may say, yes, this is the pill, and it has this kind of a mark on it.

THE COURT: Would you rely on that?

THE WITNESS: We have to at times. There are other situations where that's the only information we have. A patient may be brought into the emergency room in a coma state, as recently happened on the ward service, a patient took a good number of diabetic pills and came in a diabetic coma. And the only information we had is a big blue pill with a flat bottom, and this identified it as a specific diabetic compound.

THE COURT: What is that Physician's Desk reference with all the colors and all?

What is the purpose of that? Why do doctors have that?

THE WITNESS: The drug companies give it to you. It is established by a drug company that supports it and gives us all the medication, and has an identification section as to color and shape.

* * *

[Tr. 745] Q. I believe you also testified in other instances [Tr. 746] patients had made inquiries to you about a change in the appearance in the drug; is that correct? A. Yes.

Q. And in those instances were you able to explain to them satisfactorily so that they took the medication? A. I believe so.

Q. Do you have a close relationship with your patients? A. I should like to think so.

Q. That's important in the medical practice, is it not? A. It's important, yes.

Q. Now, is it possible, sir, that a patient who has seen you for one ailment may also be seeing another doctor? A. Yes.

Q. And in those instances could that other doctor be prescribing other medication to the patient? A. I would imagine so. I can't answer that question.

Q. And can you conceive of instances where the medication being prescribed by the other doctors identical in color and size to the medication you happen to be prescribing for the patient? A. I don't know. That might happen.

[Tr. 747] Q. Is there any way you would know? A. If the patient came back to me and showed me some pills he was taking and I recognized them as not being mine, I might inquire where he got them and find out then that another physician gave it to him. But I wouldn't know unless he showed me the pill.

Q. Now, assuming that the patient was in a situation where another doctor had prescribed a pill that happened to look similar, would that patient be in trouble if they relied on the color, the color, for example on your pill chart? A. I would have to know what the medication is that they were taking. If there was side effects, it might.

Q. What hospital are you associated with? A. The Brookdale Hospital Medical Center in Brooklyn.

Q. And are you somewhat familiar with the medications stocked in the pharmacy at Brookdale? A. Yes.

Q. And does Brookdale carry generic product in its pharmacy? A. I believe so.

Q. Do you know whether Brookdale has carried the drug amitryptline from more than one source? [Tr. 748] A. I don't know that. I am not a member of the pharmacy.

Q. Have you ever prescribed amitryptline to a patient? A. Yes.

Q. Have you ever prescribed imipramine to a patient? A. Yes.

Q. Are you aware whether imipramine comes in different colors from different manufacturers? A. Yes, because of the basic problem we discussed. A patient told me he got a different pill. When I told him he would be receiving a certain type of pill, he came back and said, "My pill looks different from that and did you give me the right medication?"

Q. Did you assure him? A. I looked it up in the PDR as to whether or not there was a different company making the pill. I looked it up and found the specific pill and the same product and tried to reassure the patient that it was imipramine.

Q. And were you successful in reassuring the patient? A. Yes.

Q. Have you ever prescribed librium for a patient? A. Yes.

[Tr. 749] Q. Have you ever prescribed librium with substitution permissible? A. I would say almost to the point — not 100 per cent, but 95 per cent I write substitution permissible.

Q. Do you know whether there are drug products on the market which are the same chemical composition as librium, but which comes in different colors? A. I am unaware of it.

Q. And you don't know whether your patient got a black and green; is that it? A. That's a color of librium, black and green.

Q. You have never gotten an inquiry from a patient? A. No.

Q. Now, do you know what kind of a drug hydrochlorothiazide is? A. Yes.

Q. What is it? A. It can typically be called a diuretic.

Q. Your deposition was taken in this case, was it not? A. Yes.

Q. Do you recall having testified that a patient who had been taking either a yellow tablet, diuretic, and [Tr. 750] was switched to a pink and he inquired about it? A. It was quite reversed. The patient was taking a pink form and inquired as to the yellow form I gave her.

Q. And were you able to reassure that patient of the change, the reason for the change? A. Yes.

Q. And do you consider it in your medical opinion a bad practice to have the same dosage form of that diuretic sold by some manufacturers in yellow and some in pink? A. I think it leads to confusion.

Q. Now, I would like to show you a Premo Catalog, Plaintiff's Exhibit 48, and show you at the top of the page, which is marked 520A, and asked if Premo in fact, according to that catalog, had sold the same diuretic in the same dosage form in those pink and yellow colors you just referred to.

(Handed to the witness.)

* * *

[Tr. 751] Q. Does it appear that it is sold in both yellow and pink? A. There is a listing on the page for hydrochlorothiazide

50 milligrams yellow, and in the next column says hydrocide tables 50 milligrams, peach.

* * *

[Tr. 752] Q. Did you ever prescribe drugs that are available in both the name brand and the generic but you prescribed them, "dispense as written"? A. Yes.

Q. And on what occasions would you? A. Diuretics particularly come to mind.

Q. You would say, "dispense as written"? A. No, I write, "substitution permitted."

Q. My question is, are there instances in which there exists on the market available both the initial name brand that was formerly patented and a range of generics?

Do you ever prescribe the name brand and sign, "dispense as written"? A. I have never done that.

Q. You don't do that.

Now, assuming you write a prescription for a patient, Doctor, how do you know that the pharmacy has, in fact, filled the prescription properly?

How would it be called to your attention if it did not? A. The patient might come to my office a month [Tr. 753] or two later and show me his pills. I might say, that doesn't look like it is a correct pill.

Or the patient might call me up and tell me what I gave him was not helping his condition.

I might ask him to come in again and show me what he is taking.

Q. It would have to be a communication from the patient to you? A. What I tell you now is hypothetical, because I can't remember an incidence of this occuring.

Q. Now, do you know whether the Physicians Desk Reference that the Court asked you about depicts all of the drugs accurately or are the appearances sometimes not quite right? A. The appearances are not always right — exactly right. I would say that most of the time they're almost good facsimiles.

About two years ago there was a problem with their color scheme and they sent us a new insert and told us to get rid of the old one. This happened about two years ago.

* * *

[Tr. 755]Q. Now, let's assume you had one of the blue-whites on your patient pill board, take this three times a day with a glass of whater [sic].

What if that patient were on both of those, could that patient reasonably rely on your pill board? A. In several different ways, probably. One, there would be a difference in the use of the specific drug. It would tell him it's under the tongue or by the mouth. It might be a different schedule of times. Maybe instead of once a day by this pill you might take this one four times a day.

If possible, I have the drug identification — either the company name or the logo or the number and the patient would likely see — if he looked that there is a different number or a different name —

Q. In other words, you would have to inspect these two blue and white pretty closely if he were on both of those drugs; is that correct? A. He would have to inspect them if someone gave him two pills that looked alike.

THE COURT: Would you give him a chart with two pills that look identical like that?

THE WITNESS: It is most unlikely. But I was asked if another physician would. We do ask our [Tr. 756] patients what medication they're on already. I see patients from another physician with a collection of pills. I am somewhat aware of the medication that the patient is already taking.

Q. Reliance on color could cause problems? A. As a single facet, yes.

Q. Have you ever known of a situation — an overdose situation involving vasodilators?

THE COURT: Can you get an overdose so that you will be in trouble?

THE WITNESS: I can't answer that, I don't know.

* * *

Q. What is the number that appears on the pills — what does that number indicate? A. The number on the pill is the company's identification of the specific product. Not only the name of the product, but also the strength of the product.

* * *

[Stempel, Tr. 764] Q. Now, after World War II were there any advertising of drugs to the public? A. You're talking about prescription —

Q. Ethical drugs? A. Prescription drugs are not advertised to the public because it is not in the province of the consumer to purchase drugs without prescriptions.

Q. After World War II generally, were prescriptions [Tr. 765] written for drugs identified by brand name or a generic or chemical name?

I am talking about the period right after World War II. A. They were mostly by trademark designation or brand names or proprietory designation, which are synonomous.

Q. After World War II if a pharmacist — and I am talking about the period right after World War II, received a prescription for a brand name drug, did he have any discretion on how he filled the prescription? A. Would you repeat the question?

Q. After World War II when a pharmacist received a prescription calling for a brand name drug, did he have any discretion in the manner in which he filled the prescription? A. No, he had to fill it in accordance with the physician's direction.

THE COURT: Were the generic drugs on the market at that point right after World War II?

THE WITNESS: To a limited extent.

Q. Prior to the substitution laws, were many prescriptions written for generic drugs? A. Very few.

Q. Why was this? [Tr. 766] A. There was no demand in the light of, as there is in the present, in the light of existing substitution laws or what is more — what is more usually called drug product selection laws.

Q. Has there been a trend one way or the other recently with respect to prescriptions calling for generic drugs as distinct from brand names? A. There has been a up trend. If I could cite statistics — by '66 there were approximately — I say approximately without giving the decimal places — approximately six percent of generics throughout the country.

Based on total prescription volume and it rose in 1978 to thirteen plus which I round off to approximately fourteen plus or minus and therefore it provides an impact of approximately twice over a twelve year span as far as increase in generics are concerned.

* * *

[Tr. 770] Q. Since 1949, when you became a licensed pharmacist, to your knowledge, has there been a practice — a general practice with respect to — generic drugs products and their appearances vis-a-vis, corresponding trademark products? A. Since I have been practicing pharmacy I have found that the generic products usually have the same or similar appearnace [sic] as the branded products.

* * *

[Tr. 774] Q., Do you have an opinion, Dr. Stempel, as to whether or not Exhibit 4 shows the general practice of generic pharmaceutical manufacturers with respect to the appearance of the drugs they make, vis-a-vis trademark products? A. Yes.

I believe it does show the general appearance of generic products as compared to trademark products.

Q. Have you worked as a dispensing pharmacist since 1949 on occasion? A. Yes.

From 1949 until 1972.

Q. Based on your pharmaceutical experience, do you have an opinion as to what purpose the color is insofar as a patient is concerned, with respect to his medication?

* * *

A. As far as the purpose of the medication for the consumer, it indicates to the consumer the purpose, the therapeutic purpose for which he is to utilize, use said medication.

[Tr. 775] Q. Have you ever observed the patient checking his refill prescription medication that you have dispensed to him? A. Yes, I have.

Q. Based on your observation what was the patient doing? A. The patient was — wanted to be assured that he was obtaining the same medication on a refill that he had originally obtained.

Q. Have you ever had a patient request of you the name of the manufacturer of a drug product? A. Never.

Q. Are generic drugs detailed to your knowledge? A. Generic drugs are not detailed.

Q. How is the demand for generic drugs created if they are not detailed? A. The stimulus for the manufacture of generic drugs is based upon the drug product selection laws which have recently been instituted.

* * *

[Tr. 781] Q. Now, in connection with the drugs that you have provided, did you in any instance attempt to ascertain whether the particular drug in the same size dosage was also available on the market in colors different from what was on the chart? A. No, I did not.

Q. Do you know whether in fact some of the drugs shown on the chart do in fact come in different colors? A. They do.

Q. Do you know how many of them come in different colors? A. I don't know.

Q. Were you asked only to collect the look-alikes and not to collect the entire range of prescription drugs in each category? A. My request was to obtain look-alikes.

Q. Only? A. Yes.

Q. Do you know where the students you referred [Tr. 782] to obtained these look-alikes? A. These students obtained look-alikes from the pharmacies in which they were employed.

Q. Do you personally know whether any of the drug products on that chart are actually available in pharmacies today? A. I believe I have already answered that question, and the answer is I don't know.

MS. DRISCOLL: I ask your Honor that Exhibit 4 not be received in evidence.

THE COURT: No.

I'll receive it. If you want to tell me which ones are not right there and which ones have different colors, I will consider that too.

MS. DRISCOLL: We will be doing that on rebuttal.

THE COURT: Yes.

Q Now, I refer to the pharmacist's exam, Dr. Stempel, which has been marked as Defense Premo 3. A. That's correct.

Q. Now, turning to page 2, is hydralazine a generic or a trademark? A. In this case I believe it is a generic designation.

* * *

[Tr. 784] THE COURT: Do you know of your own knowledge, leaving out what you heard from other folks proctoring, do you know from your own knowledge what 25 miligrams [sic] hydralazine comes in, what color?

THE WITNESS: I don't know.

I have never seen it.

Q. Do you know whether 25 miligram [sic] hydralazine in fact comes in more than one color? A. I don't know.

Q. When they put Ciba down in the little box there, that means that they have filled the prescription with hydralazine made by Ciba? A. If it is generic it requires the name of the manufacturer or the distributor of. If it is a trademark designation, according to law it only requires the trademark designation, which obviously everyone knows is the ownership of the specific company, if it has a specific strength.

THE COURT: So when they saw draw a circle around the color of the medication dispensed, you would have to know the color of Ciba's hydralazine, what it was?

THE WITNESS: Yes, your Honor, yes, sir.

* * *

[Tr. 793] THE COURT: Let's take this one on page 4.

THE WITNESS: Yes, all right, Nitro-Bid.

THE COURT: And let's assume that Eric Dahl, MC., signs substitution permissible.

THE WITNESS: Yes.

THE COURT: Now, he fills it with a generic.

And let's assume he puts on the label the [Tr. 794] name of the company.

THE WITNESS: And the generic name?

THE COURT: And the generic name.

THE WITNESS: Yes.

THE COURT: Does he also have to put on the label anything about the doctor having given him permission?

THE WITNESS: No.

THE COURT: Orally given him permission?

THE WITNESS: No.

But he should make that notation on the original prescription paper.

THE COURT: All right.

THE WITNESS: And he should also explain it to the patient.

THE COURT: All right.

Q. Now, do pharmacists from time to time advise people in the pharmacy, consumers, about over-the-counter medications that might be useful for given ailments they are asked about? A. Yes.

Q. Is there a certain relationship confidence that exists between pharmacists and the patient consumer? A. Assuming that the patient patronizes the [Tr. 795] same pharmacy continuously, the answer is yes.

Q. Now, is a pharmacist in the State of New York required to pass along to the consumer the saving after having dispensed a generic drug, as opposed to the more expensive name brand? A. In New York State the present law does not provide for the passing on of cost-savings.

Q. Now, do you have any knowledge of how a pharmacist would determine what price to charge a patient for a prescription drug? A. I am not an expert on prescription pricing.

But in essence there are two methods. There is the mark-up method and the professional fee method.

Q. And would you describe for the court each method?

First, the mark-up. A. I don't think I am in a position to explain mark-up. But I am in a position to explain professional fee because I am an advocate of the professional fee concept.

* * *

[Tr. 812] THE WITNESS: If this contains cyclandelate then the pharmacist should have on the prescription label the word cyclandelate with the manufacturer [Tr. 813] or distributor's name thereon, without perusing it any further.

* * *

Q. You're saying they're not properly labeled; is that correct? A. I am saying that they're not labeled in accordance with the manner in which they should be labeled. Assuming there is cyclandelate generic in each?

Q. Yes, assuming that. A. I'd like to point out that this is labeled —

THE COURT: Which one is that?

Q. The number is on the bottom. A. 82TT. It is mislabeled. However, if one can state it is mislabeled — it is not as — mislabeled as badly as some of the others.

THE COURT: Why do you say that?

THE WITNESS: Because in this specific case [Tr. 814] the name of the manufacturer is listed but the point is it is mislabeled, your Honor. In this case — this stands together.

82BB are not too bad as compared to this, on a comparative evaluation basis. Here again, I would say these five are mislabeled and this is also mislabled but it is not mislabeled as badly as the other five.

* * *

[Tr. 815] Q. In questioning by Miss Driscoll, there was a statement made about trade names or brand names belong to particular companies.

When a pharmacists sees or hears the name of a [Tr 816] drug product, does the pharmacist usually know whether the name is a generic name or a brand name? A. He usually knows.

Q. Now, if it is a trade name, does the pharmacist usually know which company owns the trade name? A. Not necessarily. He may have to consult a suitable text, the American Drug Index.

Q. And your experience, do patients when they see or hear the name of a drug usually know whether it is a generic name or a trade name? A. They don't know anything. They don't usually know anything concerning medication.

* * *

THE COURT: You say the pharmacist usually will know whether a drug is — the name that is on the prescription is a brand name or a generic name?

When you say usually, I take it sometimes he doesn't?

THE WITNESS: Yes.

THE COURT: Is it a problem educating people [Tr. 817] about what the generic name is?

THE WITNESS: There are so many advances that it is difficult to keep up with the times. If he sees a specific name and he's not aware of it, he can consult the American Drug Index which will indicate to him whether it is a trademark designation or not.

THE COURT: Take some of those bottles and assume for the moment, which we don't know one way or the other, assume for the moment that the druggist is within perfectly good faith, and assume for the moment that it said — the prescription said, "substitution permitted."

Could that be — and they put in cyclandelate — is that possible that they — that they thought that the Cyclospasmol was the generic name?

THE WITNESS: I believe, your Honor, they did this in good faith. I believe the law is still in its infancy as far as its span of time that it has been invoking and we really can't condemn the pharmacist. He gave the patient the generic. It just that he may not be fully aware —

THE COURT: What is the reason for him to mislabel it unless he's trying to — unless he does [Tr. 818] it deliberately? What is the reason for him to mislabel it and put in cyclandelate, in your experience?

THE WITNESS: I believe it takes time to be familiar with all the intricacies of the law and he may not be knowledgable concerning the intricacies of the law.

* * *

[Tr. 819] THE COURT: That was the one where it was for Cyclospasmol and they came and they gave them cyclandelate.

They were allowed because it said, "substitution permissible" but they put on the label Cyclospasmol.

Here is one that says generic Cyclospasmol which would seem to indicate, perhaps wrong — perhaps I am wrong, but would seem to indicate that they think — I won't speculate.

THE WITNESS: May I say something?

I believe this is with good intent. I can cite specific examples as I have in my deposition where novobiocin sodium was prescribed to a patient and an unscrupulous pharmacist gave a cold capsule —

* * *

THE COURT: What could they have been supposing if they were in good faith?

[Tr. 820] THE WITNESS: They were supposing that they were providing the patient with the correct medication and they may not have been knowledgable concerning the intricacies of the labeling.

* * *

[Calodny, Tr. 822] Q. Is there a hospital policy or guideline which you follow when purchasing drugs for the hospital? A. Yes.

We have a hospital therapeutic committee [Tr. 823] for the hospital and a board of directors.

And they informed me to purchase at the best possible price and to save money for the institution.

Q. Are you a member of the pharmacy committee? A. Yes.

I am the Secretary of the Pharmacy Committee, and I also conduct the meetings of the pharmacy committee.

Q. Do you purchase generic drugs in accordance with the guidelines set forty by the committee? A. Yes.

Q. Do you follow any particular practice when you purchase generic drugs? A. Yes, I do.

I try to purchase generic drugs from companies that have representatives where at least I can determine the quality of the product and how it is manufactured.

At least I could have somebody to relate to. And I also visit pharmaceutical companies on occasion to visit their manufacturing processes.

Q. When you purchase these generic drugs, do you look for them in any particular characteristic? A. Yes.

I try to purchase the generic medication, [Tr. 824] so that it looks in the same size, shape and color as the original brand.

Q. And would you give the court a few examples of some of the generics that you purchase? A. We have the Chlorpheniramine.

THE COURT: Before you go on listing those, what kind of hospital is yours?

Is it a general hospital?

THE WITNESS: Yes, it is, your Honor.

It is a general hospital, a proprietary hospital. We have mainly a geriatrics population of the hospital.

THE COURT: Thank you.

You were going to give us other examples.

THE WITNESS: Yes.

I also purchase Rauwolfia Serpentina that resembles Robaxin.

I also purchase Basocodyl that resembles Dulcolax.

Q. And I take it you purchase some others too? A. Yes, quite a few.

* * *

[Tr. 825] Q. The ones you listed, are they the same size, shape and color as the brand name? A. Yes.

Q. And in your experience what is the benefit to you and the hospital to purchase generic drugs in the same size, shape and color as the brand name? A. It makes it easier for the purpose of identification.

I dispense a particular medication to the nurse, and she has to administer the medication to the patient.

Now, if it resembles the original brand name, there is no question about it, she is pretty certain that, well, this resembles the original brand, and there is no question in her mind that this is the proper drug.

And also the patient, who may have been on this medication before? The hospital recognizes this medication and says, yes, this looks like the proper medication for me, and the patient complies and takes the medication.

Q. Have you ever had the occasion to purchase and dispense a drug that was a different size, shape and color than the one previously purchased and [Tr. 826] dispensed and caused the problems which you just related? A. Yes, I did.

There was a time when we had in stock a brand of Beachum Totacillin.

This was a brown and orange capsule.

Then I purchased Smith, Klein & French brand of Ampicillin, which was a different color and this created problems.

Q. What were the problems that arose from dispensing the SKF brand? A. The SKF brand, and I have a sample here with me.

This was part of the problem, resembled the Macrodantin of Eaton Laboratories.

I then got calls from the nurses and some doctors, hey, is this the right medication, what are you sending us. They wanted you to confirm it.

As a matter of fact, a couple of nurses even called me at my home to question this particular medication, was this the right one.

So we did— I never purchased that brand again and I went back to the purchase of the Beachum brand of Totacillin, Ampicillin.

Q. Were there also patient problems that [Tr. 827] resulted from the switch to the SKF? A. Yes.

Some of the patients refused to take the medication, thinking that it was the wrong thing.

Now we have, as I mentioned before, primarily a geriatric population at the hospital.

And a lot of these people are very finicky.

And if you give them something that doesn't look like they are accustomed to taking, they will refuse to take this medication.

* * *

How do you know that the patients refused to take this medication? A. Since we have a small hospital some of the nurses would notify me verbally, and also on the patient medication chart they will indicate on the medication sheet, refused, patient refused medication.

Q. And you noticed this with regard to the SKF brand? A. Yes. We did see cases of this.

[Tr. 828] Q. Did you report this incident regarding the confusion? A. Yes.

I spoke with my sales representative from the SKF Company, and informed him that your product looks identical to the Macrodantin of Eaton.

And I said, this created quite a confusion at the hospital, and would you please get back to your sales people and to your production people and notify them that this is causing these problems.

Q. Macrodantin is different from Ampicillin? A. Yes.

It is a different chemical and used for a different purpose.

Q. Before writing prescriptions are there occasions where a doctor would consult the pharmacist regarding the availability of a particular drug? A. Yes.

On occasions I had physicians calling me and requested a particular brand because they had an old patient, and this man or woman is accustomed to taking a particular medication that looks in a particular way.

And if this varies in some way they say that this patient would not take the medication.

[Tr. 829] An example of this was the Parke Davis brand of Dilantin which has an orange brand around it. And the doctor requested me to take this particular brand because he knew if we attempted to use some generic brand that didn't look like it the patient would refuse to take it.

Q. Is Dilantin a short term for long-term drug? A. A long-term drug usually used in epileptic cases to prevent seizures.

And if the patient doesn't take this medication serious effects could result.

Q. As an experienced pharmacist, do you have an opinion as to the use of look-alike drugs used for long-term? A. I definitely feel that a medication that is of the same size, shape and color as the original would certainly be accepted and taken by the patient.

This aids in patient compliance in my opinion. And therefore the benefits of the medication are therefore given to the patient.

Q. Are you familiar with Forrest Laboratories? A. Yes.

[Tr. 830] They are a generic drug manufacturer.

Q. And you purchase generics from Forrest? A. Yes, I have.

Q. Would you just name one or two? A. I have purchased a nitro glycerine capsule and a hydrochlorithiacide tablet.

Q. Is that the same size, shape and color as the brand name? A. Yes.

They are the same brand name.

Q. Are you aware of a drug that was sold by Forrest with the name Cyclanfor? A. Yes.

That is a generic cyclandelate.

Q. Do you know what color Cyclanfor was? A. That was a green color.

Q. Are you familiar with Cyclospasmol? A. Yes.

Q. And what color is that? A. That is the —

Q. The 200 or 400 miligram [sic]. A. The 200 miligram [sic] is blue, a blue capsule, and the 400 miligram [sic] is a blue and red capsule.

Q. Now, how did you become familiar with the [Tr. 831] Forrest Cyclanfor product? A. In October of '77 I attended the New York State Council of Hospital Pharmacists Convention.

At that time it was held at Tanament in the Poconos, and Forrest Laboratories had a booth at the convention.

And I spoke with one of the salesmen and he informed me they had a cyclandelate which was in a green color.

Q. Did you purchase that cyclandelate in the green color? A. No, I didn't, because this incident with the SKF penicillin was still fresh in my mind, and I said, I prefer not to purchase this in a green color.

I would like it in a blue color.

Q. To your knowledge is Cyclospasmol a long-term drug? A. Yes. This is usually used as a long-term drug, yes.

Q. Are the hospital purchasing records for Parsons Hospital categorized by drugs? A. No. They are categorized only by company.

* * *

[Tr. 832] Q. Are you familiar with the brand name for Amitripolene? A. Yes.

Q. What is that? A. Elavil.

Q. Do you know what color Elavil is sold? A. Elavil is in six different strengths. Each strength has a different color and each tablet has a little different shape.

Some are larger and some are smaller.

Q. Is there a different color for each dosage strength? A. Yes. There is definitely a different color for each dosage strength.

Q. Do you know who makes Elavil? A. It is made by the Merck, Sharp & Dohme Company.

[Tr. 833] Q. Do you know how Merck, Sharp & Dohme promotes its various colors in industry publications? A. Yes.

They show the pictures of the different tablets, and they show that each one, each strength has a different and distinctive color.

Q. Does that color serve to identify each tablet? A. Yes, definitely.

* * *

[Tr. 835] Q. Do you ever use the Physician's Desk Reference? A. Yes, I do.

Q. What do you use it for? A. Well, I am often in my work — I act as a consultant to nurses and physicians. So am often asked questions about particular medications, as to what their usages are, what their adverse reactions are, or sometimes a patient might develop an allergic reaction and the doctor would wish to know, did this particular drug cause this particular reaction or is it possible that it occurred.

THE COURT: Do you ever use the photographs?

THE WITNESS: In the physician's desk reference?

THE COURT: Yes.

THE WITNESS: Yes.

THE COURT: What do you use them for?

THE WITNESS: I use them, as I would, as I had mentioned before, if I wish to use a generic I want to make sure that the generic looks like the original.

THE COURT: All right.

Q. I refer you to what has already been marked as Plaintiff's Exhibit 32, which is the 1979 edition of [Tr. 836] desk reference, and ask if on page 421 there is a Parke Davis product with an orange band?

Is that the product which you testified about on direct? A. Yes, this one here.

Q. And I draw your attention to the footnote on that page, and ask if it makes any reference to the banded product which you just referred to. A. It says the color combination of banded capsules is a Parke Davis trademark.

Q. Had you ever stocked in your pharmacy a generic product which was not a look-alike? A. Yes.

Q. Now, I believe you testified that you have purchased from Forrest Laboratories two generic products, hydrochlorothiazide and nitroglycerine. A. Yes.

Q. Do both of those products in the form you purchased them from Forrest have the same appearance as the name brand product? A. Yes, they do.

* * *

[Olson, Tr. 838] Q. Are you employed? A. Yes, I am.

Q. By whom? A. By IMS America Limited.

Q. How long have you been employed by IMS? A. I joined them in August a year ago, 1978.

Q. And can you briefly describe what business IMS is in? A. IMS is a world-wide organization whose prime purpose is to collect and disseminate information relative to prescribing patterns of physicians, treatment patterns of physicians, as well as drug, hospital, federal government purchase of pharmaceutical type and health care type products.

* * *

[Tr. 843] Q. Now, can you determine based upon the information from your Audatrex sample and any report of prescriptions in that sampling for Cyclospasmol, approximately how many physicians in the United States do prescribe Cyclospasmol? [Tr. 844] A. Yes, we can.

Q. What is your estimate? A. In the range of about 15,000.

Q. Did you give that information, you being IMS, to Dr. Lipstein? A. Yes, we did.

Q. Now, I will show you what I have marked as Plaintiff's Exhibit 127 through 129 and simply ask you to identify briefly what these are?

(Documents shown to the witness.)

A. Plaintiff's Exhibit 127 is a therapeutic category report which is one of the reports of the National Prescription Audit. It is the issue date December '76.

Information displayed in here are prescriptions as written by physicians for the years 1974, '75, and '76, and for the months July through December of '76.

Q. Does that specifically show the number of prescriptions written for Cyclospasmol? A. Yes, it does.

Q. Would you turn to the next exhibit?

THE COURT: How many for Cyclospasmol does it show?

THE WITNESS: In the year 1976 for the full year there was approximately 159,000 new prescriptions, 1,352,000 refill prescriptions —

* * *

Total prescriptions, 1,911,000.

Q. Could you identify the next two exhibits also, as briefly as possible? A. Plaintiff's Exhibit 128 is a therapeutic report National Prescription Audit for the period ending December of '78.

Q. Does that show similar information about Cyclospasmol? A. Yes, it does.

Q. And Exhibit 129? A. Exhibit 129 is from the National Prescription Audit Therapeutic Category Report for the period ending October 1979.

Q. And that shows Cyclospasmol also? A. '79, yes, that also shows Cyclospasmol.

Q. Now, do you have a practice or policy at IMS as to whether or not the names of any patients or physicians that might have participated in your data gathering activities remain confidential? A. They must remain totally confidential.

* * *

[Shinbach, Tr. 859] Q. In your professional career as a psychiatrist, could you estimate what percentage of your patients were over 60 years of age? A. Approximately 70 per cent.

Q. During the past two years can you estimate what percentage of your patients have been suffering from cerebral arteriosclerosis? A. Of the 70 per cent I would say two-thirds have had cerebral arteriosclerosis, or indications of that condition.

Q. Can you tell the Court what some of the symptoms a person would exhibit if he was suffering cerebral arterisclerosis [sic]? A. The typical symptoms of that condition are confusion, disorientation, memory impairment, cognitive impairment, by which I mean certain kinds of disorders with the thought process, including impaired judgment, poverty of information, that kind of thing. And in addition impairment of affect, by which we mean the regulation of mood is also characteristic of that condition.

Q. Is Cyclospasmol a drug which is sometimes prescribed for persons suffering from cerebral arteriosclerosis? A. Yes.

Q. Would you describe what effect Cyclospasmol [Tr. 860] would have on such a person? A. Well, in theory and in the hopes of a physician, it's intend [sic] to dilate the cerebral arteries, increase the blood supply to the brain and improve a marginal situation of imparied [sic] oxygen supplied to the brain.

Q. Have you ever prescribed Cyclospasmol to any of your patients? A. I have on a few occasions.

Q. What general age group were the persons for whom you prescribed Cyclospasmol? A. These are people in their 70 to 90 year range.

Q. Were these persons frequently taking more than one medication? A. Quite frequently.

Q. Could you describe what other types of medications such patients might be taking? A. Yes.

Very often a person who has artery impairment in the cerebral arteries would have arterial impairment in coronary arteries, vessels to the kidney and other organs. So such a patient might be taking one or more cardiac medication, such as a digitalis preparation and possible Inderal. They might be taking a diuretic or electrolites or a coronary artery dilator. That would be a typical situation.

[Tr. 861] Q. How many of these drugs might a typical patient with cerebral arteriosclerosis be taking at the same time or say during the same day? A. Well, it's not uncommon that a person might take all of them. But very frequently a person might take two or three from that group.

Q. Are some of these or many of these patients self-medicating? A. Certainly some of them are.

Q. And are some of the patients who are self-medicating exhibiting the symptoms of cerebral arteriosclerosis as you described previously? A. To a greater or a lesser degree, yes.

[Tr. 862] Q. And in your opinion is it safe for such persons to be self-medicating? A. It may not be entirely safe; in some cases where the forgetfulness, let's say it's minimal, it may be safe enough.

Even when it is entirely safe there may be no alternative when you are dealing with a person who is widowed, isolated and unable to afford nursing care and so forth.

Q. Are there potential danger if one or more of this — of these multiple drugs are taken on an incorrect schedule? A. Yes, there are many great dangers.

Q. Can you describe what they might be, under what circumstances? A. Well, for example, if the patient were taking Cyclospasmol three times a day, and instead, because of confusion, took digitalis three times a day, there could be any range of complications from mild disorientation to death.

It could be very serious.

* * *

[Tr. 863] Q. To your knowledge have patients who are taking multiple medications during any given day ever fallen into this problem of confusing one medication for another? A. Oh, yes, definitely.

* * *

Q. Have you ever treated a patient who was taking more than one medication, and was in the habit of carrying various pills or the forms of medications in a single unmarked container? A. Yes.

[Tr. 864] That's rather common.

Q. Is this a practice that you encourage? A. No.

Q. Well, what do you do when you come across a patient who is doing such a thing? A. Well, if they are getting along all right with that system and it is working for them, I don't interfere, although I would not recommend it.

If they are confusing the medication in some way or seem to be in danger of making a confusion like that, then I attempt to get them to keep the medication separate by type.

Q. Has it ever occurred that you made such an attempt but the patient has continued with his previous practice? A. Oh, yes.

I have in mind one such patient who is very proud of her enameled and very beautiful pill box and likes to carry them that way.

Q. In communicating with a patient during a consultation during the subject of prescription drugs that the patient may be taking, do you or the patient ever use the appearance of the drug to describe it? A. That's not infrequent.

[Tr. 865] Q. Can you describe how that might come about? A. Very often the patient will not be familiar with the generic or the brand name of the patient and he will tell me, I am taking these white heart medicines from my internist, Doctor so and so.

And you are the doctor who gave me my yellow medicines for my mood.

And another doctor gave me this or that for gout.

Q. Does the appearance of the drug ever become used in instructing the patient on the use of it? A. Yes.

Psychiatrists have found that it is best to talk to patients in their own language.

So when a patient speaks to me in pill colors, I respond in the same idiom.

* * *

[Tr. 867] Q. Does the color of the drug ever come up in these particular consultations? A. Yes.

In what way? A. Well, for instance, even a patient who is given a vial with a label on it, a brand-name on the label would say that is the yellow pill I take three times a day.

Q. In your experience, have you observed the patients use the color of their pills to stay on schedule? A. They do.

Q. Have you ever had a patient who was taking two or more pills that had the same general appearance in color, but were different medications? A. Yes.

Q. Has this ever caused confusion in the patient? A. It led to considerable confusion in a number of instances, and one I remember recently, and that is the one I referred to in the deposition.

Q. Could you describe that one? A. This was a patient with, an elderly woman with an agitated depression. She lived alone. She was widowed.

[Tr. 868] She had a concerned social worker who saw her once a month, for her agitated depression.

I prescribed Mellarill, 10 miligrams [sic]. That is the brand name.

She was to take a total daily dose of six a day of those.

She mixed it up because the Mellarill is a green-yellow, even to me with fairly good eyesight looks similar to the yellow Elavil.

There is a difference if you look closely in the right light.

And the size is about the same.

So she was taking three a day, six a day of the antidepressant and three a day of the other instead of the six I prescribed.

As a result she became confused. Her blood pressure dropped and she was falling. The depression far from feeling became worse. Her agitation became worse. Her vision was more blurred. She was less able to distinguish the medicines.

It was a vicious cycle of effects that compounded one another. And the social worker called me in a complete panic when she found the woman bruised from falling, et cetera.

[Tr. 869] THE COURT: What did you do?

THE WITNESS: The social worker also not being accustomed to drugs, was confused as to which drug was which drug.

We figured it out. Amazingly she had gotten the drugs into the wrong vials. We did work it out.

The social worker Scotch-taped the proper pill to the proper vial. I thought this was ingenious. And in time the woman did get it straight. It did not happen automatically though.

Q. Are some of the patients you are treating taking maintenance drugs? A. Many.

Q. And what is a maintenance drug? A. A maintenance drug is a drug which a patient takes on a prolonged basis, and the feeling is without continued ingestion of that drug, maintenance on that chemical, the person's condition would recur.

* * *

[Tr. 870] Q. What effect does the color have on the patient? A. Well, I think the sameness of color helps to keep from disrupting the patient's habits.

They feel that they are doing the right thing. It is an established regimen with them.

They go through the paces day after day taking these necessary medications without a second thought, which is by far best with many of these patients.

Q. What do you think would happen if a patient received a refill of the prescription in a different color or in a different appearance? A. It would call for adjustment and establishment of new patterns which could be difficult with a patient with some confusional state.

Q. Have you run across such patients that have received pills they were previously taking in one form, and somehow or another the same drug has been offered to them in a different capsule or tablet. A. Yes. That does happen.

Q. And what does the patient think about?

* * *

[Tr. 871] Q. What did they tell you they thought about? A. I hear about it because they come to me and complain. They call and complain. They suspect that the pharmacist has given them a wrong drug, filled a prescription incorrectly.

They suspect that I have written the wrong dosage. They think something is wrong and they want to know what is going on.

As a matter of fact, as the physician I also when I first hear it, my first hunch is that something is going on, and later on it turns out that it was correctly filled but with a different product.

Q. You say this has happened to you in your actual practice? A. Yes.

Q. Can you relate any examples? A. It happens with my in-patient practice, not infrequently, because that is because the pharmacist of the hospital is totally in charge of what is dispensed.

The hospital by-laws allow a physician to prescribe by brand name, but it will be filled generically in this day of cost consciousness in hospitals.

[Tr. 872] So I never know what the patient will get if I prescribe a certain drug.

At least I don't know, but I do know the chemical. That I am sure of.

So if the patient comes into the hospital and gets a medication they have been buying by brand name, and the hospital fills it with another product of the same type, I will get questions about that.

And they say, you said you will continue me, you are changing my medication, why, this has worked so well, the nurses are making a mistake, that kind of thing.

And if it is an out-patient they call and I have to check with the pharmacist and the secretary has to confirm whether it is the same substance.

Q. Have you ever had a case that the patient ever thought that the other drug was not working the same as the original drug, although it is the same chemical and different appearances? A. I have had a number of cases where the patient has said these were more affluent patients than normal, but they say, look, Doc, if you are giving me something just because they are cheaper and it is not as good, I don't want you to spare money, this is [Tr. 873] important, this is important to me or she is my wife, whatever the situation may be.

Q. And does any particular drug come to mind where this has happened?

I was asking you for a specific instance if you can remember one, if not just tell us that. A. This happens in a lot of different situations. It happens to psychiatrists a great deal, at least it did with Lithium.

Q. What is Lithium? A. A salt related to common table salt. It comes out of the ground and not made in the laboratory. It is used for manic depressant illness.

No patent was able to be used by — for Lithium to my knowledge, because it wasn't made by any company. And it was in existence for thirty years and used here and in Europe for different reasons.

So three big companies jumped into the market, at least three I would say, with their own size and shape and form of Lithium.

One was a capsule. One is a tablet, a large tablet of a different color, and there is another one which I think is a capsule of a different color still.

So I write Lithium and the druggist fills [Tr. 874] it according to his preference.

And if a patient has been in one pharmacy or the druggist or supplier changes, I get a call as to what is going wrong.

Q. After you get that call what would the nature of the conversation be, or what has the nature of the conversations been between you and a patient who questions the drug for that reason. A. Again, am I getting the correct thing, is it the right side [sic], will it hurt me to take it.

Q. What do you tell the patient? A. Once I have confirmed that it is the correct chemical, I tell them it is really the same although it is a tablet and a capsule, and although it is a different color and so forth.

Q. After that explanation is given, are there generally future problems with respect to refilling the prescription and the patient's reaction to it? A. Probably not, unless they then get the third preparation of Lithium and have the same question again.

Q. Have you ever worked in an emergency room of the hospital? A. Yes, I have.

[Tr. 875] Q. Could you describe under what circumstances? A. I rotated through the emergency room at the Montefiore as an intern, and Gracie Square maintains a small emergency room where I have been called on occasions over the past ten or twelve years.

Q. Have you been present ever when a patient suffering from an apparent drug overdose was brought into the emergency room? A. Yes.

Q. Could you describe the procedure of such a case? A. Well, it depends on the patient's condition.

We see a number of suicidal patients. A patient might walk in saying they are — have taken an overdose or might be carried in unconscious.

If they are unconscious and their respiration is failing and you are concerned about their life you go right to work on that, and then ask questions later.

If they are alert and tell you they have taken an overdose, then you get as much information then as you can before instituting treatment.

Q. Is it important at one point or another during this emergency procedure to identify the drug or [Tr. 876] drugs the patient has taken? A. It is highly desirable, yes.

Q. Why is that? A. Certain drugs have specific adverse effects when taken in excessive amounts.

For instances, the barbiturates are infamous for depressing respiration.

So if a person comes in and has OD'd on phenobarbitol, you know that you want to have a resuscitator there, you want to have oxygen there. You might want to call the cardiac team which is especially well-equipped for that type of situation.

You might want to call an anesthesiologist. If a person has been sniffing — that is not an overdose, but if a person has taken too much digitalis, it would have primarily cardiac effects and you might want to alert the dialysis unit, that sort of thing.

Q. In the process of identifying the drug or drugs which that emergency patient has taken, is color of the drug ever used, and if so, how? A. Well, you use every possible clue. And color could be very important. It might be the only thing.

A family member or a policeman or an ambulance driver might say, I don't recall know, Doctor, [Tr. 877] but I saw these white pills lying all over the floor, or these yellow capsules.

Of course, if you can make a more definite identification of the substance, if you are lucky enough to see the actual capsule and you can track down the identification number, if you know the patient from your own clinic or you know the doctor and you know what has been prescribed for that patient, that is the best.

But in a great many instances, we are in essentially an articulate situation where nothing but sight identification might be there to help you.

Q. Are there any charts or aids commonly kept in emergency rooms for which such a sight identification might be helpful? A. Yes, there are.

In the PDR courses, manual, it is the primary source.

Q. How does the PDR help? A. It has a product identification section with many or most available products pictured there.

Q. In your experience as a doctor, have you ever known a patient who associated the color of a drug with its manufacturer? [Tr. 878] A. That is not common. Most people really don't care about the manufacturer.

Q. With what do they associate the color of the drug? A. With the effect of the drug.

That color pill is for my heart. That is for my gout. That sort of thing. That is for my diabetes. They associate it with the doctor who gave it to him.

Sometimes they associate it with a therapeutic effect or a pleasant side effect.

* * *

[Tr. 880] Q. And what was the dosage for Elavil? A. Twenty-five milligrams.

Q. Did you know at the time that you prescribed them that they were both yellow tablets? A. If I had thought about it I would have known, but it didn't occur to me until the problems arose.

Q. Could there be situations in which patients see you for one problem and then see another doctor for another problem? A. Very often.

Q. Is it possible that those patients who see another doctor subsequently would receive medication about which you would have no knowledge? A. Yes, it is.

Q. Now, in addition to this case of the Mellaril and the Elavil, both of which are yellow, are you aware of any other drug products on the market which are different medications but which are the same colors? A. Yes.

Q. Are you also aware of the existence in the market of the same medication in the same dosage form, but in different colors? [Tr. 881] A. In some case I am aware of that.

Q. Have you ever prescribed Librium? A. Certainly.

Q. And when you prescribe it, do you prescribe, "dispense as written"? A. No.

Q. I show you what I have marked as Plaintiff's Exhibit 135, and ask if one of the products on that sheet appears to you to be Librium?

(Exhibit shown to the witness.)

A. Yes.

Q. Which one? A. The one beside the Hoffman-LaRoche.

Q. How did you recognize the Librium? A. It is black and green and I see the third one is also black and green, but I don't recall Librium having a CF on it, if that is the mark.

Q. Do you recognize any of the other capsules on 135? A. No, I don't.

Q. In your experience, have any of your patients for whom you prescribed Librium received a color other than green and black for that dosage form? A. I don't recall it being mentioned to me.

[Tr. 882] Q. Now, have you ever prescribed any barbiturates in your practice? A. Very rarely.

Excerpts of Trial Proceedings

Q. Have you prescribed barbiturates that come in different colors? A. Yes, I have.

Q. Have you ever had any problem with patient receptivity to the different colored barbiturates? A. Yes, I have.

Q. And have any patients ever refused to take the barbiturates because of the color change? A. I have had patients who have refused until they have discussed the matter with me and assured themselves that it was correct.

Q. After they spoke to you they had no problem; is that correct? A. I believe so.

Q. Have you ever prescribed in your practice an antidepressant called Amitriptyline hydrochloride? A. Yes.

Q. How would you prescribe that, by a brand name or otherwise? A. I prescribe that both ways, but most frequently I use the name Elavil.

[Tr. 883] Q. What color is that? A. It has three different colors depending upon the dosage size.

* * *

[Tr. 888] Q. Do you have a special person that buys drugs? A. Yes.

Q. Do you know what criteria they use? A. There is a list published by New York State of approved generic equivalents and from that list she chooses, I am sure, the least costly alternative.

Q. Is it your understanding that it is based upon costs? A. In the end, it is, yes.

Q. Do you know whether at the present time the source of the particular medication may be changed, namely one manufacturer one year, another the next year? A. No, the physicians wouldn't know that.

* * *

[Lipstein, Tr. 906] Q. Dr. Lipstein, would you recall that a suggestion was made that an alternative way to have acquired the names of persons throughout the United States who were users of Cyclospasmol would have been to make a telephone call.

Did you consider using that method? A. Well, a very rapid computation would demonstrate the outlandish and unreasonable nature of that kind of result. There are roughly 100,000 patients who are on Cyclospasmol. There are 80 million households in the United States. If one simply divides one by the other we get one in 800 people who are on Cyclospasmol.

To find 100 patients for interview purposes would have required identification or talking to [Tr. 907] 80,000 households.

THE COURT: Or 800.

THE WITNESS: From one in 800, it would turn it up to 80,000 multiplying it by 100.

Because of the incident rates we know in order to complete a single telephone interview one must make approximately six dialings. So multiply the 80,000 times six gives us 480,000 dialings.

Number one, the cost of that would probably exceed a million dollars. But even more important than that is that I do not believe there is a single research company in the United States who could execute such a study.

Therefore, it is absolutely an unfeasable method of finding people who are on Cyclospasmol.

Q. Sir, if you did nonetheless go to this expense and make these telephone calls, how would you find out that the person to whom you are speaking is taking Cyclospasmol? A. You would have obviously to ask them if they take Cyclospasmol, in which case you would be conditioning them when you are inquiring as to Cyclospasmol, so having gone through the million dollar expenditure you [Tr. 908] would have destroyed the possibility of doing a study because you would have conditioned them.

* * *

[Tr. 915] THE COURT: So you just got those figures, the 80 per cent, what you figured out to 80 per cent or somebody did from Heller? A. Yes, that's right.

Q. And you didn't check out the figure? A. I had no time.

Q. That was not the question A. I was not able to check it out.

Q. One other question. Are there any other figures that you testified about that you personally haven't checked out? A. I did not do the interviewing myself.

Q. I am talking about the figures A. I reviewed the tabulations that came from the tabulation house. And all those figures which I thought were important to evaluate. I might say certainly that 80 per cent concerned me and I made inquiry about it.

[Bovoso, Tr. 929] Q. Mr. Bovoso, have you reviewed the chart identified as Premo — Plaintiff's Exhibit Premo 4? A. Yes.

Q. Have you prepared a chart which shows each instance of which you are aware in which the various generics come in colors different than the name brand shown on the chart? A. Yes.

Q. I show you Plaintiff's Exhibit 130. I ask, except for the last page of that exhibit, the exhibiit, in fact, shows or lists products that you know come in colors different from the name brand on the Stempel chart? A. Precisely.

Q. Could you tell us in how many instances there are available generics in non-look alike colors, from the chart? A. I would have to count them off here.

Q. Would you count them. I don't want to have to read it in.

(Pause)

A. 37 cases that are different.

* * *

[Tr. 932] Q. When Smith, Kline sells generic products, do you know whether it uses any kind of identifying brand for its generic products? A. Sometimes they use generic names.

THE COURT: And sometimes another brand name?

THE WITNESS: If they want to call it that, I guess.

THE COURT: Another name, I should say.

Q. Looking at Exhibit 139, what is that? A. This is a picture chart of the products promoted by Smith, Kline and French in their generic SK line.

Q. Do you know if that is a current chart? A. It was February of '79. It is relatively current, to my knowledge.

Q. Have you made any attempt to determine whether Smith, Kline had products of a similar appearance in its generic line in 1977? A. Yes.

Q. How did you determine that? A. I compared this particular chart with the chart [Tr.933] that is listed in the 1977 PDR.

Q. I show you what has been marked Exhibit 137, Plaintiff's and I ask you if that is the book you used to make the determination?

(Exhibit shown to the witness.)

A. Yes, it is.

Q. What did you discover? A. That the list — this 1979 pictorial list of drugs is basically the same as it was in 1977 with a few additions to the 1970 — 1979 line.

Q. Do you know whether Smith, Kline judging from your review of the Physician's Desk Reference, and Exhbit [sic] 139 dropped any generic lines — generic products from its line? A. I could ascertain just one.

Q. Are you aware, Mr. Bovoso, of any studies done by any governmental organization in the State of New York concerning the substitution law in New York? A. Yes, the Attorney General's study done in conjunction with the Office of Consumer Affairs.

Q. I show you Exhibit 138 and I ask you if that is the study to which your're referring? A. Yes.

* * *

[Tr. 935] Q. In each instance where the reference is not in the PDR, do you have personal knowledge that the product referred to and the color referred to is, in fact, on the market? A. Yes.

Q. Looking at that same list, 130A, do you know how many of the products listed there can be considered long term medication — maintenance drugs? A. Yes, it would be easier enough to go down the list and pick them out.

Q. Could you do that quickly? A. Shall I name them or pick them out and give you an idea?

Q. Why don't you name Hydralazine. A. Hydralazine is one — cyclandelate is the next. Dexamethasone is often times used by arthritics. Amitriptyline, antidepressant. Hydrochlorothiazide, long term therapy.

* * *

[Tr. 940] Q. Were you always with Ives as a detail man? A. Yes.

Q. And is not the purpose of a detail man or detail person to go to a doctor and encourage the doctor to write specifically for the drug or the drugs of the company he works for? A. Yes, that is one of the purposes.

Q. Okay.

Now, with respect to Exhibit 139, which is the SK line, SK is Smith, Kline, is that correct? A. Smith, Kline & French.

Q. In Philadelphia? A. Yes.

Q. And they identify their drugs, do they not, with an SK; in other words, SK hydrochlorothiazide, SK Prednisolone, and SK-Prednisolone is not the generic name, the generic name is Prednisolone is that right? A. Yes.

Q. And SK details their drugs, do they not? A. Not to my knowledge. They do not detail this line of drugs.

Q. You specifically know they do not detail [Tr. 941] their drugs? A. I said not to my knowedge.

Q. For a doctor to prescribe for SK, say hydrochlorothiazide, he would have to write as on this chart, SK hydrochlorothiazide? A. If a doctor specifically wanted the SK hydrochlorothiazide, yes.

Q. Okay.

With respect to Exhibit 134, MSD, Merck, Sharp & Dohme, they detail their drugs, do they not? A. Yes.

Q. And Abbott Labs details their drugs? A. Yes.

Q. And Ciba details its drugs? A. Yes, they do.

Q. And they all try to get the doctor to write for their specific brand of hydrochlorothiazide? A. I don't know that.

Q. Okay.

With respect to Amitriptyline hydrochloride, Hoffman LaRoche details its drugs, do they not? A. Yes.

Q. And Warner details its drugs, do they not? A. Yes.

Q. And U.S. Vitamin, on Imipramine, they [Tr. 942] detail their drugs, do they not? A. Yes.

I don't know if they specifically detail Imipramine.

Q. As far as you know they detail their drugs, is that right? A. Yes, they do.

Q. Papaverine hydrochloride, who is Saron? A. I have no idea.

Q. Central Pharmacy, have you ever heard of them? A. Only from picking the name out of a book, but I never saw them detail their product.

Q. How about Mayrand? A. I never saw them detail a product either.

Q. That was not the question I asked you.

I asked you who they were. A. I picked them out of a book.

Q. Marion. A. I think Marion Labs.

Q. And they detail their drugs, do they not? A. Yes, they do.

Q. Who is Key Pharmaceuticals, have you ever heard of them? [Tr. 943] A. Yes, I have.

Q. And what is the nature of their business? A. I think they detail. They vary, sometimes detailing and sometimes not detailing.

Q. Lemmon Pharmaceutical Company? A. Yes.

Q. They detail, don't they? A. I have never met a Lemmon representative.

Q. So you don't know if they do or they don't. A. That's right.

Q. Are you familiar with Savage Laboratories? A. No.

Q. And Schering Laboratories, or Schering Plough I guess they are called? A. I know their sales people.

Q. They detail? A. Yes, they do.

MR. COBRIN: For the record, I am going through 130A.

Q. Warner/Chilcott details, do they not? A. I have met their sales people.

Q. Stuart Pharmaceuticals details, do they not? A. Yes, they do.

* * *

[Desiderio, Tr. 966] Q. And do you know approximately how many of the people who are entitled to use the out-patient facilities of the Medical Center are elderly? A. We have approximately 5,500 members who take advantage of our center, who are retired members of the industry, and they are over 65.

Q. Does the pharmacy at the Sidney Hillman Medical Center stock generics? A. We are 100 percent generic. Since we established the decision to go generic, it is at least ten years now.

Q. And do you know whether from time to time the pharmacy and the Sidney Hillman Medical Center has changed the source of a particular medication from one company to another. A. Yes.

* * *

[Tr. 970] Q. Do you have the speciality, a speciality in your private practice, Doctor? A. Well, because of — I do internal medicine, but I have been taking care of people beyond the age of 65 for the last 15 years, I guess, ten or 15 years, and they comprise about 75 percent of my practice.

I have to say I have a special affinity for people in that age group.

Q. Have you also treated young people from time to time? A. Yes, I do.

Q. Do you have any opinion as to one age group manifests more confidence and reliance in the physician than another age group? A. My opinion is that the so-called geriatric population, particularly those above 70, have a greater reliance and a greater respect for th eopinion of the physician.

Q. Now, in your private practice had you ever had occasion, have you ever had an occasion when the color or the appearance of a drug was changed on a patient? A. Yes.

Q. And had you had inquiries as to that? A. Yes.

[Tr. 971] If a patient is hospitalized, and during this hospitalization he is given certain medication and on discharge his initial prescription is filled, and this happens when I refer a patient for in-patient therapy. And on leaving the hospital the prescription is filled for the first time at a neighborhood drug store. And then the patient comes to me at the center or comes to my office for a new prescription.

* * *

And in many instances — well, at times when the patient is discharged from the hospital for a prescription for digoxin, and I will change it to Lanoxin. And the patient will ask if it is the same [Tr. 972] as they received in the hospital. And I will say, yes, it is just a different company.

Q. And the patients generally accept the explanation? A. Yes.

* * *

Q. You say your hospital was 100 percent generic? A. We are not a hospital.

Q. The Sidney Hillman — A. Yes, the medical center.

Q. It is one hundred percent generic? A. Yes.

Q. Why is it generic as distinguished from brand names? A. We have a special prescription program for our retirees, whereby they pay one half the price — one half the cost of the prescription. And the maximum there that can be charged for any prescription is $2.00. So the Board of Directors, we have a peculiar Board of Directors, and they are involved, very well involved in the finances of our [Tr. 973] clinic, particularly since half of them are making contributions towards the support of the clinic. And we have quite an overhread in our pharmacy. And they want to convert it to the generic form to really save money so we will not go bankrupt.

* * *

[Tr. 974] Q. So when Smith, Kline and French supplies your tetracycline it is always the same color because it comes from Smith, Kline and French; is that right? A. Yes. But before that we had the different color, the plain orange color, I think, from Squibb.

Q. Tetracycline is not a maintenance drug, is it? A. No, it's not a maintenance drug. But our biggest conversion was to switch from the Papaverine hydrochloride. When we switched from Cerespan to Papaverine we had a contract with Cerespan for at least three years and we switched to Papaverine.

Q. Doctor, has your office of the Sidney Hillman Foundation — the Sidney Hillman Medical Center, been visited by SKF detail men? A. Yes.

* * *

Q. Doctor, before a patient will come to you to tell you, to get reassured about a change in color, has the pharmacist first tried to convince him that he is getting the same drug? [Tr. 975] A. Yes.

Q. And apparently the patient does not accept the pharmacist's explanation when he comes to you? A. This is a rare occurrence.

Q. But it occurs? A. I have an image at our center that — this is not an ego session on my part, but the older people have a great of — we have a mutual love affair going on. All right. An 80 year old or many of the 80 year olds would come to the clinic mainly because I am there. It is difficult maybe for you to appreciate this love affair between me and my elderly patients, I am sure. And some of them go to the extremes in this thing and say unless Dr. Desiderio says it I will not do it. This is not the unusual. This is the usual circumstance.

* * *

Q. What kind of product is this Papaverine you have just referred to? A. A maintenance drug for circulatory insufficiency, used for cerebral arterio insufficiency.

[Tr. 976] Q. You indicated in response to one of Mr. Cobrin's questions that you have been visited in the Center by detail men from Smith, Kline and French; is that right? A. Yes.

They come to my office as well as the pharmacy.

Q. Have they ever discussed their generic line? A. No.

* * *

Q. Has Smith, Kline and French ever left any literature to you about their generic line? A. No.

Q. Have you ever received any literature about their generic line? A. I don't.

Q. Has the pharmacy? A. He has a file about everything.

* *

[Kashickey, Tr. 983] Q. What do they do with the price list? A. Well, we get a solicitation from them. And we send a price list to them, and if it meets with their approval, issue us an award.

So I have an installation who wishes to make a purchase can do so through this price list which has a contract number attached to it.

Q. Do you know whether the federal government takes steps to encourage pharmaceutical companies to enter into the bidding situation? A. Yes, they do.

If a particular item is within a company's price list and if it enjoys a pretty good movement, in other words, the VA or any one of the facilities, they purchase an awful lot of it, they will communicate, they will take the initiative and communicate with that company and try to enter into some sort of agreement, a negotiated contract.

When they do this, they will depot or stock inventory items at three locations throughout the United States, at any VA installation, Public Health Service Hospital, hospitals in Indian reservations, et cetera.

They can take advantage and purchase it from the depot.

Q. Now, to your knowledge, does there exist any [Tr. 984] federal government specifications in connection with the Cyclospasmol, cyclandelate, requiring it to be in a particular color? A. No.

Q. I now show you Exhibit 141 and ask you if you can identify it.

MS. DRISCOLL: Your Honor, I have blocked out the price because of the confidentiality.

These are prices that Ives uses for bidding in government contracts.

THE COURT: Do you bid at a lower price than what you sell to the customer, to the ordinary consumer?

THE WITNESS: Sometimes, your Honor.

It depends on the quantities involved.

THE COURT: It would depend on quantities, whether in effect you give them a quantity discount.

THE WITNESS: To a degree.

We don't bid every single solitary item in our line.

Q. Can you identify Exhibit 141, Mr. Kashickey (handed to witness) A. This is one of the sheets of a solicitation [Tr. 985] that we have received from the Veterans Administration asking us to submit a quotation on Isosorbide nitrate, 40 milligrams.

* * *

[Tr. 986] Q. Now, have you ever sold Cyclospasmol cyclandelate to any state government? A. We do.

Q. And do you know whether there is any state which makes any reference to the color of the product to be purchased? A. Out of 50 states there is only one reference and that is the state of New Jersey.

Included in their solicitation is a reference that the color must be blue.

Q. Do you sell any of your Isordil to the State of New Jersey? A. Yes, I do.

Q. And do you know if Stuart Pharmaceutical Company sells Sorbitrate to the State of New Jersey? A. Yes.

Q. And are Isordil and Sorbitrate the same drug?

THE COURT: Do you mean the same chemical?

MS. DRISCOLL: Yes.

* * *

[Tr. 988] Q. And do you have any knowledge as to whether any of these local governmental agencies make any reference to color in connection with cyclandelate? A. No, they don't.

* * *

Q. As I understand your answer to Court's question, the bids list the drugs by generic name; is that correct? A. That's correct.

Q. Well, I notice that — do you prepare this information on the sheet 141? You type any of it in? A. Just — you know, the packing material and the unit price and the amount.

* * *

Q. Well, where it says Cyclospasmol under cyclandelate, who typed that in? A. That's the Veterans Administration.

[Tr. 989] Q. And they typed that in, do they not, so there is a reference for cyclandelate and they'll know what product they are talking about? A. That's right.

* * *

Q. Mr. Kashickey, to your knowledge, will the State of New Jersey accept a bid where the manufacturer offers cyclandelate in a color that's not blue? A. Judging from past history, with regard to our Isordil ten milligram, versus a Sorbitrate ten milligram, I would think that they would accept a bid from another manufacturer if the color was other than blue.

THE COURT: But they don't — they don't specify color as to that, do they?

THE WITNESS: They do in the State of New Jersey.

THE COURT: On your Isordil —

THE WITNESS: No, no. They don't specify it in the —

THE COURT: All right.

Q. Are you familiar with a federal standard for capsules for medicinal purposes? A. No, I am not.

* * *